

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

BEDFORD COUNTY,

Plaintiff,

vs.

PURDUE PHARMA L.P.; PURDUE
PHARMA INC.; THE PURDUE
FREDERICK COMPANY, INC.;
TEVA PHARMACEUTICALS USA, INC.;
CEPHALON, INC.; JOHNSON &
JOHNSON; JANSSEN
PHARMACEUTICALS, INC.;
NORAMCO, INC.; ORTHO-MCNEIL-
JANSSEN PHARMACEUTICALS, INC.
N/K/A JANSSEN PHARMACEUTICALS,
INC.; JANSSEN PHARMACEUTICA,
INC. N/K/A JANSSEN
PHARMACEUTICALS, INC.; ENDO
HEALTH SOLUTIONS INC.; ENDO
PHARMACEUTICALS, INC.;
MCKESSON CORPORATION;
CARDINAL HEALTH, INC.; RICHARD
S. SACKLER; JONATHAN D.
SACKLER; MORTIMER D.A. SACKLER;
KATHE A. SACKLER; ILENE SACKLER
LEFCOURT; BEVERLY SACKLER;
THERESA SACKLER; DAVID A.
SACKLER; RHODES TECHNOLOGIES;
RHODES TECHNOLOGIES, INC.;
RHODES PHARMACEUTICALS L.P.;
RHODES PHARMACEUTICALS, INC.;
TRUST FOR THE BENEFIT OF
MEMBERS OF THE RAYMOND
SACKLER FAMILY; THE P.F
LABORATORIES, INC.; STUART D.
BAKER; ALLERGAN PLC F/K/A
ACTAVIS PLC; WATSON
PHARMACEUTICALS, INC. N/K/A
ACTAVIS, INC.; WATSON
LABORATORIES, INC.; ACTAVIS, LLC;

C.A. No. _____

(Removal from: The Court of
Common Pleas of Delaware County)

ACTAVIS PHARMA, INC. F/K/A
WATSON PHARMA, INC.; PAR
PHARMACEUTICAL, INC.; PAR
PHARMACEUTICALS COMPANIES,
INC.; MALLINCKRODT PLC;
MALLINCKRODT LLC; SPECGX LLC;
ANDA, INC.; CVS HEALTH
CORPORATION; RITE AID OF
MARYLAND, INC., DBA RITE AID MID-
ATLANTIC CUSTOMER SUPPORT
CENTER, INC.; RITE AID
CORPORATION; WAL-MART INC.;
INSYS THERAPEUTICS, INC.;
AMNEAL PHARMACEUTICALS, LLC;
ECKERD CORPORATION;
ROCHESTER DRUG CO-OPERATIVE,
INC.; VALUE DRUG,

Defendants.

NOTICE OF REMOVAL

In accordance with 28 U.S.C. §§ 1331, 1332, 1441, 1446, 1453, and 1367 with full reservations of defenses, including its objection to personal jurisdiction, Defendant CVS Health Corporation gives notice of the removal of this action originally filed in the Court of Common Pleas of Bedford County, Pennsylvania and now pending in the coordinated proceedings located in the Court of Common Pleas of Delaware County, Pennsylvania to the United States District Court for the Eastern District of Pennsylvania. In support of removal, CVS provides this “short and plain statement of the grounds for removal.” 28 U.S.C. § 1446(a); *see also Dart Cherokee Basis Operating Co., LLC v. Owens*, 135 S. Ct. 547, 553 (2014) (“By design,

§ 1446(a) tracks the general pleading requirement stated in Rule 8(a) of the Federal Rules of Civil Procedure.”).

I. NATURE OF THE REMOVED ACTION.

1. The complaint in this case is substantively identical to *Adams County v. Purdue Pharma L.P., et al.*, Case No. 2:19-cv-04438-JS (E.D. Pa., 2019), which CVS removed on September 20, 2019, and was transferred by the Judicial Panel on Multidistrict Litigation to the Opiate MDL pending in the United States District Court for the Northern District of Ohio on February 5, 2020. JPML Dkt. No. 7035.

2. On February 20, 2020, Plaintiff Bedford County, Pennsylvania (“Plaintiff”) borrowed the *Adams County* complaint and filed it under its own name in the Court of Common Pleas of Bedford County, Civil Division, for claims relating to prescription opioid medications. The case was later transferred to the consolidated proceedings located in the Delaware County Court of Common Pleas. Plaintiff alleges claims against two defendant groups (“Defendants”): Manufacturer Defendants and Distributor Defendants. As a subset of the Distributor Defendants, Plaintiff notes that Defendants CVS, Rite Aid, and Walmart¹ shall be referred to as “National Retail Pharmacies.”²

3. Plaintiff brings claims related to prescription opioid medications,

¹ Plaintiff named Wal-Mart Inc. as a defendant to this action; as of February 1, 2018, Wal-Mart Stores, Inc. became known as Walmart Inc., not Wal-Mart Inc.

² See Complaint ¶ 136 (“Cardinal, McKesson, Rochester Drug Co-Operative, Anda, Value Drug, and the National Retail Pharmacies are collectively referred to as the ‘Distributor Defendants.’”).

including claims for (1) consumer fraud and deceptive practices under the Pennsylvania Unfair Trade Practices and Consumer Protection Law (“UTPCPL”); (2) public nuisance; (3) negligence; (4) unjust enrichment; (5) common law fraud; (6) civil conspiracy for deceptive marketing; and (7) civil conspiracy for unlawful distribution practices. Plaintiff seeks damages and equitable relief for alleged injuries to the residents of Bedford County.

4. This action is one of approximately 2,600 opioid lawsuits filed by government entities against manufacturers, distributors, and retailers of prescription opioid medications. Plaintiff alleges that Defendants are liable for the economic and non-economic injuries suffered by Plaintiff and its residents, including physicians treating residents and employees, and opioid-addicted individuals.

5. On December 5, 2017, the Judicial Panel on Multidistrict Litigation created a Multidistrict Litigation in the Northern District of Ohio (the “Opiate MDL”) for cases just like this one—cases in which “cities, counties and states . . . allege that: (1) manufacturers of prescription opioid medications overstated the benefits and downplayed the risks of the use of their opioids and aggressively marketed . . . these drugs to physicians, and/or (2) distributors failed to monitor . . . and report suspicious orders of prescription opiates.” *In re Nat’l Prescription Opiate Litig.*, MDL No. 2804, Dkt. No. 1 (Dec. 12, 2017 Transfer Order) (attached hereto as **Exhibit 1**). To date, approximately 2,000 actions have been transferred to the Opiate MDL.

6. Plaintiff's 271-page Complaint resembles virtually all of the complaints filed in the Opiate MDL. The bulk of the allegations in these complaints have been levied by counties against the manufacturers for alleged deceptive marketing of prescription opioids from approximately the 1990s to present. In fact, the allegations against the manufacturers and distributors here are nearly identical to those asserted in *The County of Summit, Ohio, et. al. v. Purdue Pharma L.P., et al.*, MDL No. 17-md-2804, Case No. 1:18-op-45090, a bellwether case currently being litigated in the Opiate MDL.

7. In addition, Plaintiff's Complaint is nearly identical to the Complaint filed by the same Plaintiff's counsel and removed to this Court by Defendant Walgreens on December 31, 2018. *County of Carbon v. Purdue Pharma L.P.*, No. 2:18-cv-05625, E.D. Pa. Dkt. No. 1 (E.D. Pa., Dec. 31, 2018). On March 12, 2019, Chief Judge Juan R. Sanchez stayed proceedings pending decision on transfer by the JPML. In doing so, Chief Judge Sanchez recognized that "a stay would promote judicial economy by conserving the parties' resources, avoiding duplicative litigation, and preventing inconsistent rulings." *See id.*, E.D. Pa. Dkt. No. 51. (Walgreens later consented to remand of the Carbon County action while that action was pending in the Opiate MDL. But nothing about that remand affects the removability of this action or changes the analysis of whether similar actions should also be transferred to the Opiate MDL.)

8. The gravamen of Plaintiff's Complaint is that certain so-called Manufacturer Defendants made various "misrepresentations" regarding the safety

and efficacy of opioids that were subsequently distributed “though various channels, including through advertising, sales representatives, [and] purportedly independent organizations,” in order to “convince physicians, patients, and the public at large of the truth of each of these propositions . . . [and] to expand the market for their opioids.” Complaint ¶¶ 199-201.

9. Plaintiff also alleges that certain Distributor Defendants “distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes.” Complaint ¶ 110. According to Plaintiff, Distributor Defendants “universally failed to comply with federal and/or state law,” which, Plaintiff alleges, “is a substantial cause for the excessive volume of prescription opioids plaguing Plaintiff’s Community and of the diversion of prescription opioids into Plaintiff’s Community.” *Id.*

10. Based on these allegations, Plaintiff claims a litany of injuries to its residents stemming from the alleged abuse of addictive opioids by residents in Bedford County. These include alleged damages in the form of expenses expended for medical insurance claims for opioids that were not medically necessary, as well as increased costs of social services, emergency services, health systems, law enforcement, and treatment facilities. *E.g.*, Complaint ¶ 946.

II. BASIS OF REMOVAL

A. FEDERAL QUESTION

11. Removal is proper under 28 U.S.C. §§ 1441 and 1331 because Plaintiff's claims present a substantial federal question under the Controlled Substances Act ("CSA"), 21 U.S.C. §§ 801, *et seq.*).

12. The original jurisdiction of the district courts includes jurisdiction over "all civil actions arising under the Constitution, laws, or treaties of the United States." 28 U.S.C. § 1331.

13. "Whether a case 'arises under' federal law for purposes of § 1331" is governed by the "well-pleaded complaint rule." *Holmes Grp., Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826, 830 (2002).

14. Even when state law creates the causes of action, a petition may raise a substantial question of federal law sufficient to warrant removal if "vindication of a right under state law necessarily turn[s] on some construction of federal law." *Merrell Dow Pharm. Inc. v. Thompson*, 478 U.S. 804, 808-09 (1986) (quoting *Franchise Tax Bd. v. Constr. Laborers Vacation Tr.*, 463 U.S. 1, 9 (1983)); *Gully v. First Nat'l Bank*, 299 U.S. 109, 112 (1936) ("To bring a case within [§ 1441], a right or immunity created by the Constitution or laws of the United States must be an element, and an essential one, of the plaintiff's cause of action.").³

³ CVS need not overcome any artificial presumptions against removal or in favor of remand. In *Breuer v. Jim's Concrete of Brevard, Inc.*, 538 U.S. 691 (2003), the Supreme Court unanimously held that the 1948 amendments to the general federal removal statute, 28 U.S.C. § 1441(a), trumped the Court's prior holdings in *Shamrock Oil & Gas Corp. v.*

15. “[F]ederal jurisdiction over a state law claim will lie if a federal issue is: (1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress.” *Gunn v. Minton*, 568 U.S. 251, 258 (2013); see *Grable & Sons Metal Prods., Inc. v. Darue Eng’g & Mfg.*, 545 U.S. 308, 315 (2005). “Where all four of these requirements are met . . . jurisdiction is proper because there is a ‘serious federal interest in claiming the advantages thought to be inherent in a federal forum,’ which can be vindicated without disrupting Congress’s intended division of labor between state and federal courts.” *Gunn*, 568 U.S. at 258 (quoting *Grable*, 545 U.S. at 313-14).

16. When a purported state law claim is premised on violations of duty contained in a federal statute, a federal court has jurisdiction over that claim. See

Sheets, 313 U.S. 100 (1941), and its antecedents that federal jurisdictional statutes must be strictly construed against any recognition of federal subject matter jurisdiction, with every presumption indulged in favor of remand. *Id.* at 697-98 (“[W]hatever apparent force this argument [of strict construction against removal] might have claimed when *Shamrock* was handed down has been qualified by later statutory development. . . . Since 1948, therefore, there has been no question that whenever the subject matter of an action qualifies it for removal, *the burden is on a plaintiff to find an express exception.*” (emphasis added)); see also *Exxon Mobil Corp. v. Allapattah Servs., Inc.*, 545 U.S. 546, 558 (2005) (construing 1990 enactment of 28 U.S.C. § 1367, authorizing supplemental federal subject matter jurisdiction, and holding: “We must not give jurisdictional statutes a more expansive interpretation than their text warrants; but it is just as important not to adopt an artificial construction that is narrower than what the text provides . . . Ordinary principles of statutory construction apply.” (citation omitted)).

More recently, a unanimous Supreme Court in *Mims v. Arrow Financial Services, LLC* held: “Divestment of district court jurisdiction’ should be found ‘no more readily than ‘divestment of state court jurisdiction,’ given ‘the longstanding and explicit grant of federal question jurisdiction in 28 U.S.C. § 1331.’” 565 U.S. 368, 379 (2012) (alterations omitted) (quoting *ErieNet, Inc. v. Velocity Net, Inc.*, 156 F.3d 513, 523 (3d Cir. 1998) (Alito, J., dissenting)).

Bd. of Commissioners of Se. La. Flood Protection Authority-East v. Tenn. Gas Pipeline Co., 850 F.3d 714, 722-23 (5th Cir. 2017) (concluding that federal question jurisdiction exists because claims were premised on the failure to satisfy a standard of care established in federal statute). Federal jurisdiction is established if there is no “state law grounding for the duty that the [plaintiff] would need to establish for the Defendants to be liable,” because the absence of any such state source “means that the duty would have to be drawn from federal law.” *Id.* at 723. A claim premised on the breach of such a duty “cannot be resolved without a determination whether . . . federal statutes create [such] a duty,” and therefore necessarily raises a federal question. *Id.*; *see also Hughes v. Chevron Phillips Chem. Co.*, 478 F. App’x 167, 170-71 (5th Cir. 2012) (plaintiff’s state law claims gave rise to federal question jurisdiction because resolution of claims relied on duty contained in federal law).

17. As set forth below, Plaintiff’s tort claims meet all four requirements.

18. Although Plaintiff ostensibly pleads some of its theories of recovery against CVS as state law claims, it bases the underlying theory of liability on CVS’s alleged violations of federal law or alleged duties arising out of federal law, specifically the CSA.⁴

⁴ Plaintiff relies on the Pennsylvania Controlled Substance, Drug, Device, and Cosmetic Act (“PCSA”), 35 P.S. § 780, *et seq.* Complaint ¶ 522. But this statute does not establish a duty to report or halt suspicious orders. For example, Plaintiff cites 35 P.S. § 780-112(c) for the proposition that the PCSA “require[s] the Distributor Defendants to ‘design and operate a system to disclose . . . suspicious orders of controlled substances . . . Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.’ 35 P.S. § 780-112(c) (incorporating 21 C.F.R. § 1301.74(b)).” *Id.* at ¶ 525. But 35 P.S. § 780-112(c) does not contain the above-quoted language. It merely requires persons registered under the PCSA to “keep records and maintain inventories in

19. For instance, Plaintiff pleads that CVS and the other Distributor Defendants violated federal law with, among others, the following allegations:

- a. Distributor Defendants were “required to register with the DEA to . . . distribute Schedule II controlled substances. *See* 21 U.S.C. § 823(a)-(b) These Defendants were further required to take steps to halt suspicious orders. These Defendants violated their obligations under federal law.” Complaint at ¶ 521.
- b. “Distributor Defendants . . . failed to monitor for, report, and prevent suspicious orders of opioids as required by federal and state law.” *Id.* at ¶ 1029.
- c. “The Defendants also had reciprocal obligations under the [federal] CSA to report suspicious orders of other parties if they became aware of them.” *Id.* at ¶ 571.
- d. “Under the [federal] CSA, pharmacy registrants are required to ‘provide effective controls and procedures to guard against theft and diversion of controlled substances.’” *Id.* at ¶ 692 (quoting 21 C.F.R. § 1301.11).
- e. “Because pharmacies themselves are registrants under the [federal] CSA, the duty to prevent diversion lies with the pharmacy entity, not the individual pharmacist alone.” *Id.*
- f. “Defendants have several responsibilities under state and federal law with respect to control of the supply chain of opioids. First, they must set up a system to prevent diversion, including excessive

conformity with the record-keeping, order form and inventory requirements of Federal law and with any additional regulations the secretary issues.” 35 P.S. § 780-112(c). And even if it did, such language would only bolster CVS’s argument that suspicious order reporting duties stem from federal law, not state law.

Plaintiff further claims that, under the PCSA and the Pennsylvania Wholesale Prescription Drug Distributors License Act (“WPDDLA”), 63 P.S. § 391, *et seq.*, the “Distributor Defendants are required to establish effective controls against suspicious orders to prevent prescription drugs from being diverted into the community, including . . . [r]eporting suspicious orders of controlled substances, including prescription opioids, to alert regulatory and law enforcement officials when it appears that prescription drugs are being diverted for illegal use” Complaint ¶ 526. But again, neither statute requires the reporting of “suspicious orders.”

volume and other suspicious orders. . . . Further, they must also stop shipment of any order which is flagged as suspicious” *Id.* at ¶ 533.

- g. “Despite their legal obligations as registrants under the [federal] CSA, the National Retail Pharmacies allowed widespread diversion to occur—and they did so knowingly.” *Id.* at ¶ 699.
- h. “Defendants continued to pump massive quantities of opioids despite their obligations to control the supply, prevent diversion, report and take steps to halt suspicious orders.” *Id.* at ¶ 678.
- i. “The National Retail Pharmacies failed to take meaningful action to stop this diversion despite their knowledge of it and contributed substantially to the diversion problem.” *Id.* at ¶ 689.
- j. “Defendants had a duty not to breach the standard of care established under Pennsylvania law and the federal [CSA] and its implementing regulations to report suspicious prescribing and to maintain systems to detect and report such activity.” *Id.* at ¶ 954.

20. The source of the asserted legal duties to prevent diversion and to monitor, investigate, and report suspicious orders of controlled substances is the CSA and its implementing regulations. *See* 21 U.S.C. § 823(b), (e); *id.* § 832; *id.* § 842(c)(1)(B); 21 C.F.R. §§ 1301.71, .74(b).

21. The source of the asserted legal duty to suspend shipments of suspicious orders is 21 U.S.C. § 823(b) and (e), as interpreted by the Drug Enforcement Administration (“DEA”) of the United States Department of Justice. The DEA interprets the public interest factors for registering distributors under the CSA, 21 U.S.C. § 823(b) and (e), to impose a responsibility on distributors to exercise due diligence to avoid filling suspicious orders that might be diverted to unlawful uses. *See Masters Pharm., Inc. v. DEA*, 861 F.3d 206, 212-13 (D.C. Cir.

2017) (citing *In re Southwood Pharm., Inc.*, Revocation of Registration, 72 Fed. Reg. 36,487, 36,501, 2007 WL 1886484 (DEA July 3, 2007), as source of DEA’s “Shipping Requirement”).

22. Plaintiff’s theories of liability against CVS and the other Defendants, as pleaded in the Complaint, are thus predicated on allegations that Defendants breached alleged duties under the CSA to implement effective controls against diversion and to detect and report “suspicious” orders for prescription opioids.

23. The federal question presented by Plaintiff’s claims therefore is “(1) necessarily raised, (2) actually disputed, (3) substantial, and (4) capable of resolution in federal court without disrupting the federal-state balance approved by Congress.” *Gunn*, 568 U.S. at 258.

24. **First**, Plaintiff’s state law claims “necessarily raise” a federal question. That is because Plaintiff’s asserted right to relief under state law necessarily requires resolution of a federal question. *Virgin Islands Hous. Auth. v. Coastal Gen. Constr. Servs. Corp.*, 27 F.3d 911, 916 (3d Cir. 1994) (“[A]n action under 28 U.S.C. § 1331(a) arises only if the complaint seeks a remedy expressly granted by federal law *or if the action requires construction of a federal statute*, or at least a distinctive policy of a federal statute requires the application of federal legal principles.”) (emphasis added); *Bd. of Commissioners of Southeast Louisiana Flood Protection Agency—East v. Tennessee Gas Pipeline Company, L.L.C.*, 850 F.3d 714, 722-23 (5th Cir. 2017) (federal question necessarily raised where negligence and public nuisance claims relied on the court’s interpretation of the scope of a duty of care contained in

federal law); *Hughes v. Chevron Phillips Chemical Co., LP*, 478 F. App'x 167, 170-71 (5th Cir. 2012); *see also N. Carolina ex rel. N. Carolina Dep't of Admin. v. Alcoa Power Generating, Inc.*, 853 F.3d 140, 146 (4th Cir. 2017) ("Regardless of the allegations of a state law claim, 'where the vindication of a right under state law necessarily turns on some construction of federal law,' the claim arises under federal law and thus supports federal question jurisdiction under 28 U.S.C. § 1331." (alteration omitted)); *NASDAQ OMX Grp., Inc. v. UBS Securities, LLC*, 770 F.3d 1010, 1021-23 (2d Cir. 2014) (a duty derived from the Exchange Act to operate a fair and orderly market underpinned plaintiff's contract and tort claims and therefore necessarily raised a federal question).

25. Plaintiff's claims against CVS and the other Distributor Defendants require Plaintiff to establish that Defendants breached duties established exclusively under federal law by failing to monitor, investigate, and report shipments of otherwise lawful orders of controlled substances or by otherwise failing to maintain controls against diversion.

26. The Complaint entirely fails to cite any Pennsylvania statutory or regulatory provision imposing a duty on dispensers of prescription medications to "monitor prescription orders," in the dispensing of prescription opioids. This is because, as explained above, these duties necessarily arise under the federal CSA and regulations.

27. While Plaintiff is the master of its petition, and it "may avoid federal jurisdiction by *exclusive* reliance on state law," *Caterpillar, Inc. v. Williams*, 482

U.S. 386, 392 (1987) (emphasis added), Plaintiff here relies on violations of federal law as the basis for its state-law claims.⁵ And Plaintiff “may not defeat removal by omitting to plead necessary federal questions in a complaint.” *Cahall v. Westinghouse Elec. Corp.*, 644 F. Supp. 806, 809 (E.D. Pa. 1986).

28. In sum, despite Plaintiff’s attempt to disguise the federal question, the Complaint necessarily raises a federal issue: whether the Distributor Defendants violated the CSA.

29. **Second**, this federal issue is “actually disputed” because the parties disagree as to the existence and scope of alleged duties arising under the CSA and whether the Distributor Defendants violated any duties arising under the CSA. Indeed, this federal issue is the “central point of dispute.” *Gunn*, 568 U.S. at 259.

30. **Third**, the federal issue presented by Plaintiff’s claims is “substantial.”⁶ “The substantiality inquiry under *Grable* looks . . . to the importance of the issue to the federal system as a whole.” *Id.* at 260. Among other things, the

⁵ Furthermore, it is not necessary for federal jurisdiction that CVS establish that *all* of Plaintiff’s counts raise a federal question. Even if Plaintiff could prove one or more of those counts without establishing a violation of federal law, this Court still has federal question jurisdiction: “Nothing in the jurisdictional statutes suggests that the presence of related state law claims somehow alters the fact that [the] complaints, by virtue of their federal claims, were ‘civil actions’ within the federal courts’ ‘original jurisdiction.’” *City of Chicago v. Int’l College of Surgeons*, 522 U.S. 156, 166 (1997). Because the Court has original jurisdiction over at least some counts against Defendant, it has supplemental jurisdiction over Plaintiff’s remaining counts against Defendant, and other Defendants, which are so related that they “form part of the same case or controversy.” 28 U.S.C. § 1367(a).

⁶ The substantiality inquiry as it pertains to federal question jurisdiction is distinct from the underlying merits of Plaintiff’s claims and has no bearing on the strength of those claims. *See Gunn*, 568 U.S. at 260 (“The substantiality inquiry under *Grable* looks . . . to the importance of the issue to the federal system as a whole.”).

Court must assess whether the federal government has a “strong interest” in the federal issue at stake and whether allowing state courts to resolve the issue will “undermine ‘the development of a uniform body of [federal] law.’” *Id.* at 260-61 (first quoting *Grable*, 545 U.S. at 315; then quoting *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 162 (1989)). As the Supreme Court explained in *Grable*, “[t]he doctrine captures the commonsense notion that a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues.” 545 U.S. at 312.

31. Plaintiff’s theories of liability necessarily require that a court determine a question relating to the important federal issue of regulation of controlled substances. Indeed, Congress designed the CSA with the intent of reducing illegal diversion of controlled substances, “while at the same time providing the legitimate drug industry with a *unified approach* to narcotic and dangerous drug control.” H.R. Rep. No. 1444, 91st Cong., 2nd Sess. (1970), *as reprinted in* 1970 U.S.C.C.A.N. 4566, 4571-72.

32. The text of the CSA itself notes that “illegal importation, manufacture, distribution, and possession and improper use of controlled substances have a substantial and detrimental effect on the health and general welfare of the American people” and that “[f]ederal control of the intrastate incidents of the traffic in controlled substances is essential to the effective control of the interstate incidents of such traffic.” 21 U.S.C. § 801. Thus, “[g]iven that . . . the plaintiffs’

claims turn on the interpretation of the federal regulations governing” the distribution of controlled substances “and the importance of those regulations to the Congressional scheme, this case plainly falls within the narrow swath of cases described in *Grable*.” *Anversa v. Partners Healthcare Sys., Inc.*, 835 F.3d 167, 174 n.5 (1st Cir. 2016).

33. Plaintiff’s attempt to enforce the CSA raises a substantial federal question even though the CSA does not provide for a private right of action. In *Grable*, the Supreme Court held that lack of a federal cause of action does not foreclose federal-question jurisdiction. The Court stated that applying *Merrell Dow* too narrowly would both “overturn[] decades of precedent,” and convert[] a federal cause of action from a sufficient condition for federal question jurisdiction into a necessary one.” *Grable*, 545 U.S. at 317; *see also, e.g., Ranck v. Mt. Hood Cable Reg. Comm’n*, 2017 WL 1752954, at *4-5 (D. Or., May 2, 2017) (state law claims based on violations of Cable Communications Policy Act raise substantial federal questions and satisfy *Grable* even though no private right of action exists under the Act).

34. Removal is especially appropriate here because Plaintiff’s action is one of thousands of similar actions nationwide, most of which are pending in the MDL in the Northern District of Ohio. Indeed, Plaintiff claims that both the “opioid epidemic” and Defendants’ alleged misconduct occurred on a national scale. *E.g.*, Complaint ¶¶ 16, 451. And Plaintiff relies on enforcement actions and settlements in jurisdictions outside of Pennsylvania to establish wrongful conduct. *E.g., id.* ¶¶ 58, 267, 542, 721-25. The MDL proceedings for the Track One-B have

substantially advanced and are set for trial in November 2020.

35. ***Fourth***, and finally, the federal issue also is capable of resolution in federal court “without disrupting the federal-state balance approved by Congress.” *Gunn*, 568 U.S. at 258. Federal courts exclusively hear challenges to DEA authority to enforce the CSA against distributors, and litigating this case in a state court runs the risk of the state court applying federal requirements inconsistently with the manner in which the federal agency tasked with enforcing the CSA—the DEA—applies them. Federal jurisdiction is therefore properly exercised under § 1331 to resolve “disputed issues of federal law” under the CSA.

36. In sum, removal of this action is appropriate because Plaintiff’s “state-law claim[s] necessarily raise a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities.” *Grable*, 545 U.S. at 314; *see also See Bd. of Commissioners*, 850 F.3d at 722-23; *Hughes*, 478 F. App’x at 170-71; *Gilmore v. Weatherford*, 694 F.3d 1160, 1176 (10th Cir. 2012) (“Although plaintiffs could lose their conversion claim without the court reaching the federal question, it seems that they cannot win unless the court answers that question. Thus, plaintiffs’ ‘right to relief necessarily depends on resolution of a substantial question of federal law.’” (quoting *Nicodemus v. Union Pac. Corp.*, 440 F.3d 1227, 1232 (10th Cir. 2006))).

37. To the extent that the Court determines that some, but not all, of Plaintiff’s claims state a substantial federal question, the Court can evaluate

whether to retain the non-federal claims against the Defendants under the doctrine of supplemental jurisdiction, 28 U.S.C. § 1367(a).

B. THIS ACTION IS REMOVABLE UNDER CAFA

38. Plaintiff's lawsuit is also removable under CAFA because: (i) litigation of this case in federal court promotes CAFA's overall purpose; (ii) the lawsuit essentially is a class action suit; and (iii) each of CAFA's statutory requirements is satisfied. Jurisdiction under CAFA is measured at the time of removal. 28 U.S.C. § 1332(d); *Anthony v. Small Tube Mfg. Corp.*, 535 F. Supp. 2d 506, 512 (E.D. Pa. 2007).

A. This is an Interstate Case of National Importance.

39. First, this lawsuit is the type of case that Congress intended to be litigated in federal court when it enacted CAFA. Congress's overall purpose in enacting CAFA was "to strongly favor the exercise of federal diversity jurisdiction over class actions with interstate ramifications." S. Rep. No. 109-14, at 35 (2005), *as reprinted in* 2005 U.S.C.C.A.N. 3, 34; *see Dart Cherokee Basin Operating Co. v. Owens*, 135 S. Ct. 547, 554 (2014) ("CAFA's primary objective is to ensur[e] Federal court consideration of interstate cases of national importance") (citations and quotations omitted); *Kaufman v. Allstate New Jersey Ins. Co.*, 561 F.3d 144, 149 (3d Cir. 2009).

40. This case is one of over a thousand cases filed across the country in which government entities have sued opioid prescription manufacturers, distributors, and others for harms arising from the abuse of these drugs. The

Opiate MDL alone has more than 2,600 individual cases that have become part of a national narrative involving opioid misuse and diversion in Pennsylvania and across the country. Plaintiff has scripted its Complaint from complaints in cases that already are being litigated in the Opiate MDL. For example, Plaintiff asserts that its claims touch upon issues of national importance, as well as duties under federal law. *See, e.g.*, Complaint ¶ 851 (citing report from the Food and Drug Administration about how opioid abuse is has been recognized “as a ‘public health crisis’ that has a ‘profound impact on individuals, families and communities across our country’”); *id.* at ¶ 854 (“A 2016 Centers for Disease Control and Prevention study estimated the national economic impact of prescription opioid overdoses, abuse and dependence to be \$78.5 billion dollars annually.”); *id.* at ¶ 976 (“As a direct and proximate result of Defendants’ negligent, willful, wanton, and intentional acts . . . there is now a national opioid epidemic that has caused enormous harm and injury to the public.”); *id.* at ¶ 521 (“Defendants violated their obligations under federal law.”).

41. As Plaintiff avers, the issues in this case implicate factual and legal issues that span well beyond State lines, and as a result, should be litigated in federal court along with the other lawsuits in the Opiate MDL for a more efficient proceeding. Indeed, in denying remand in another prescription opioid case, one court observed the following:

Here, where the opioid epidemic is pervasive and egregious, there is at least a possibility of prejudice to the defendants at the hands of a jury drawn exclusively from the very county that

is the plaintiff in this suit. A federal jury casts a wider net and is drawn from a division that comprises several counties. All may have an opioid problem, but not one that is specific to the plaintiff county.

City of Huntington v. AmerisourceBergen Drug Corp., et al., 3:17-01362, 2017 WL 3317300, at *2 (S.D. W. Va. Aug. 3, 2017).

42. Plaintiff, like the other plaintiffs in the Opiate MDL, has alleged that the distributor Defendants failed to make reports to the DEA. *See* Complaint ¶ 570 (“Defendants also worked together to ensure that . . . suspicious orders were not reported to the DEA . . .”). Accordingly, litigation of these cases requires coordination with the DEA. The Honorable Judge Dan Aaron Polster of the United States District Court for the Northern District of Ohio, presiding over the Opiate MDL, has established protocols for the DEA to provide this information.

43. In short, jurisdiction in this matter is consistent with and promotes the purpose of CAFA.

B. This Case Essentially Is a Class Action.

44. Second, CAFA applies here because this case essentially is a class action. While Plaintiff has not alleged a putative class action on the face of its Complaint, and has taken pains to contend that “[t]his action is non-removable,” Complaint ¶ 30, in reality, this lawsuit is a “class action in all but name,” *W. Va. Ex rel. McGraw v. Comcast Corp.*, 705 F. Supp. 2d 441, 452 (E.D. Pa. 2010); *see also Freeman v. Blue Ridge Paper Prod., Inc.*, 551 F.3d 405, 407-08 (6th Cir. 2008) (“CAFA was clearly designed to prevent plaintiffs from artificially structuring their

suits to avoid federal jurisdiction.”); *Mason v. Lockwood, Andrews & Newnam, P.C.*, 842 F.3d 383 (6th Cir. 2016) (noting that the “guesswork here begins with even defining the putative class, since the plaintiffs neglected to define it in their putative class-action complaint” and looking to the complaint to determine jurisdiction under CAFA). In this circuit and elsewhere, courts consistently prioritize substance and function over form when characterizing the nature of a dispute or claim . . . This is particularly true in the context of “class” or “representative” proceedings. *AT&T Mobility LLC v. Smith*, No. 11-cv-5157, 2011 WL 5924460, at *5 (E.D. Pa., Oct. 6, 2011) (quoting *Jarbough v. AG of the United States*, 483 F.3d 184, 189 (3d Cir. 2007)) (“We are not bound by the label attached by a party to characterize a claim and will look beyond the label to analyze the substance of a claim. To do otherwise would elevate form over substance and would put a premium on artful labeling.”).

45. CAFA provides that “district courts shall have original jurisdiction of any civil action in which the matter in controversy exceeds the sum or value of \$5,000,000, exclusive of interests and costs, and is a class action in which . . . any member of a class of plaintiffs is a citizen of a State different from any defendant.” 28 U.S.C. 1332(d)(2); see *Standard Fire Ins. Co. v. Knowles*, 133 S. Ct. 1345, 1348 (2013) (quoting 28 U.S.C § 1332(d)(2) and (d)(5)(B) and holding that jurisdiction exists under CAFA “if the class has more than 100 members, the parties are minimally diverse, and the ‘matter in controversy exceeds the sum or value of \$5,000,000.’”). CAFA “calls upon federal district court judges to look beyond the face

of a complaint when determining whether federal jurisdiction exists over a matter that appears to be a class action in all but name.” *W. Va. ex rel. McGraw*, 705 F. Supp. 2d at 452 (holding defendant properly removed action brought by the State of West Virginia against Comcast under CAFA because subscribers were the real parties in interest).

46. CAFA defines a “class action” as “any civil action filed under rule 23 of the Federal Rules of Civil Procedure or similar state statute or rule of judicial procedure authorizing an action to be brought by 1 or more representative persons as a class action.” 28 U.S.C. § 1332 (d)(1)(B); *see W. Va. ex rel. McGraw*, 705 F. Supp. 2d at 452. Consistent with Congress’s overall objective in favoring federal diversity jurisdiction over class actions with interstate ramifications, “the definition of ‘class action’ is to be interpreted liberally. Its application should not be confined solely to lawsuits that are labelled ‘class actions’ Generally speaking, lawsuits that resemble a purported class action should be considered class actions for the purpose of applying these provisions.” S. Rep. No. 109-14, at 35 (2005), as reprinted in 2005 U.S.C.C.A.N. 3, 34. This is true even if an action does not seek class certification. 28 U.S.C. § 1332 (d)(1)(D) (defining “class members” for purposes of CAFA as “the persons (named or unnamed) who fall within the definition of the proposed or certified class in a class action”). Courts construe complaints generously in favor of jurisdiction and should not employ any presumption against removability. *See Dart Cherokee*, 135 S. Ct. at 550 (“[N]o antiremoval presumption attends cases invoking CAFA, a statute Congress enacted to facilitate adjudication

of certain class actions in federal court.”).

47. Here, Bedford County purports to bring claims of its employees and residents “as subrogee of its employees and residents” Complaint ¶ 33. But counties cannot assert subrogation claims on behalf of residents. Rather, Plaintiff’s contention confirms that it is seeking to act as a representative for a class of residents who were allegedly harmed, either directly or indirectly, by the Defendants’ purported misbranding of opioid drugs or other misconduct.

48. Plaintiff’s Pennsylvania Unfair Trade Practices and Consumer Protection Law claim (first cause of action) is a prime example of the Plaintiff’s representative status. Plaintiff’s Consumer Protection Law claim arises from the Manufacturer and Distributor Defendants’ transactions with residents of Bedford County. *See, e.g.*, Complaint ¶ 940 (“All of this conduct, separately and collectively, was intended to deceive Pennsylvania consumers who used and paid for opioids for chronic pain”); *id.* at ¶ 935 (“Manufacturer Defendants . . . violated the UTPCPL by making and disseminating untrue, false, and misleading statements . . . to Pennsylvania and County prescribers and consumers”).

49. Elsewhere, Plaintiff emphasizes that Defendants have inflicted both economic and non-economic injuries on its residents. *See, e.g.*, Complaint ¶ 202 (“Each Manufacturer Defendant’s conduct, and each misrepresentation, contributed to an overall narrative that aimed to—and did—mislead doctors, patients, and payors about the risks and benefits of opioids.”); *id.* at ¶ 463 (“The Manufacturer Defendants created a body of false, misleading, and unsupported medical and

popular literature about opioids that . . . was likely to shape the perceptions of prescribers, patients, and payors.”); *id.* at ¶ 864 (Manufacturer Defendants’ false propositions were designed to “mislead physicians, patients, health care providers, and health care payors”); *id.* at ¶ 940 (Manufacturer Defendants’ conduct was “intended to deceive Pennsylvania consumers who used or paid for opioids for chronic pain; Pennsylvania physicians who prescribed opioids to consumers to treat chronic pain; and Pennsylvania payors, including the County, who purchased, or covered the purchase of, opioids for chronic pain”); *id.* at ¶ 945 (Defendants have “engaged in conduct or omissions which unreasonably interferes with the public health, safety, peace, comfort, convenience, or quality of life”).

50. Plaintiff’s alleged injuries derive only as a result of its residents’ alleged injuries and thus cannot be separated from the injuries that it alleges its residents have incurred. Plaintiff seeks to recover costs in providing law enforcement, medical, and social services for opioid addiction, emergencies, and overdose deaths, Compl. ¶ 974, all of which stem **only** from its residents’ opioid abuse and addiction.

51. Plaintiff’s Complaint also satisfies CAFA’s 100-member requirement because the putative class consists of thousands of residents and at least hundreds injured. *See* 28 U.S.C. § 1332(d)(5)(B). Here, Plaintiff alleges that the Defendants’ deceptive practices have caused the opioid epidemic and, in 2016, the overdose rate in Bedford County was “22.11 deaths per 100,000 residents” Complaint ¶ 860. Plaintiff further alleges that the “fatal drug overdose rate has increased in Bedford

County as much as approximately 130% between 1999 and 2016.” *Id.* Thus, the potential number of people who have been or may be affected well exceeds the 100 member requirement under CAFA.

C. Minimal diversity exists between Plaintiffs and Defendants under CAFA.

52. There is minimal diversity between Plaintiff and Defendants. District courts have original jurisdiction under CAFA of “any civil action in which the controversy exceeds the sum or value of \$5,000,000, exclusive of interests and costs, and is a class action in which . . . any member of a class of plaintiffs is a citizen of a State different from any defendant.” 28 U.S.C. § 1332(d)(2). CAFA thus eliminates the requirement of complete diversity. Instead, CAFA requires only minimal diversity—meaning that the parties are diverse if the plaintiff’s citizenship differs from that of at least one defendant. 28 U.S.C. § 1332(d)(2)(A).

53. For purposes of diversity jurisdiction, a political subdivision is a citizen of the State. *See Moor v. Alameda Cty.*, 411 U.S. 693, 717 (1973) (“[A] political subdivision of a State . . . is a citizen of the State for diversity purposes.”). A corporation is “a citizen of every State and foreign state by which it has been incorporated and of the State or foreign state where it has its principal place of business.” 28 U.S.C. § 1332(c)(1). For purposes of CAFA, the citizenship of any unincorporated association, such as limited partnerships and limited liability companies, also is determined by the entity’s State of incorporation and principal

place of business. 28 U.S.C. § 1332(d)(10).

54. Applying these principles, there is minimal diversity between the parties. Plaintiff is a political subdivision of Pennsylvania, and the putative class members are also residents of Pennsylvania. And many of the Defendants are citizens of States other than Pennsylvania. For example:

- a. Defendants Purdue Pharma Inc. and The Purdue Frederick Company, Inc. are New York corporations with headquarters and a principal place of business in Connecticut. They are, accordingly, citizens of New York and Connecticut.
- b. Defendant Johnson & Johnson is a New Jersey corporation with its principal place of business in New Jersey. Accordingly, it is a New Jersey citizen.
- c. Defendant Watson Laboratories, Inc. is a Nevada corporation with its headquarters in Parsippany, New Jersey. Accordingly, it is a citizen on Nevada and New Jersey.
- d. Defendant Cardinal Health Inc. is an Ohio Corporation with its headquarters in Ohio. Accordingly, it is a citizen of Ohio.
- e. Defendant Richard Sackler is a resident, and thus citizen, of Florida.
- f. Defendants Kathe Sackler, Jonathan Sackler, and Beverly Sackler are residents, and thus citizens, of Connecticut.
- g. Defendants Mortimer Sackler, David Sackler, and Ilene Sackler Lefcourt are residents, and thus citizens, of New York.

55. Because there is diversity of citizenship between Plaintiff and at least one Defendant, this action meets the minimal diversity requirement under Section 1332(d)(2)(A).

D. The Amount in Controversy Exceeds the Jurisdictional Limit.

56. The amount in controversy exceeds CAFA's jurisdictional threshold. Although Plaintiff alleges no specific amount of damages, "a defendant's notice of removal need include only a plausible allegation that the amount in controversy exceeds the jurisdictional threshold." *Dart Cherokee*, 135 S. Ct. at 554. In ascertaining the amount in controversy, "the claims of the individual class members shall be aggregated." 28 U.S.C. § 1332(d)(6).

57. Here, Plaintiff alleges a number of different injuries from opioid abuse and addiction. Plaintiff alleges that opioid abuse has impacted a substantial portion of their 48,480 residents at least since 2006, but potentially as far back as the late 1990s. *E.g.*, Complaint ¶¶ 3-4, 32, . Given the extent of the alleged injuries and time period, the alleged amount in controversy easily exceeds \$5 million.⁷

III. ALL PROCEDURAL REQUIREMENTS ARE MET.

58. CVS has satisfied all the procedural requirements for removal under 28 U.S.C. § 1446.

59. CVS is filing this Notice of Removal pursuant to 28 U.S.C. § 1441(a) in the United States District Court for the Eastern District of Pennsylvania, because the State court in which the action is pending, the Court of Common Pleas for Delaware County, is within this federal judicial district. This Notice is signed pursuant to Rule 11 of the Federal Rules of Civil Procedure.

⁷ The amount in controversy represents only what Plaintiff requests at this stage of the proceeding. This is not an admission that Plaintiff is entitled to recover this amount. *See Hartis v. Chi. Title Ins. Co.*, 694 F.3d 935, 945 (8th Cir. 2012) ("The removing party need not confess liability in order to show that the controversy exceeds the threshold.") (internal citations and quotes omitted).

60. CVS has not yet been served in this action; therefore this removal is timely under 28 U.S.C. § 1446(b). *See Murphy Bros., Inc. v. Michetti Pipe Stringing, Inc.*, 526 U.S. 344, 354-56 (1999).

61. In accordance with 28 U.S.C. § 1446(a), a copy of “all process, pleadings, orders, and other documents then on file in the State Court,” are attached as **Exhibit 2**.

62. In accordance with 28 U.S.C. § 1446(d), promptly after filing this Notice, CVS will “give written notice thereof to all adverse parties,” and will “file a copy of the notice with the clerk” of the Court of Common Pleas. A true and correct copy of the Notice to Plaintiff and Notice to the State Court of Filing of Notice of Removal will be filed as separate documents.

63. Under CAFA, “[a] class action may be removed . . . by any defendant *without* the consent of all defendants.” 28 U.S.C. § 1453(b) (emphasis added).

64. In accordance with 28 U.S.C. § 1446(b)(2)(A), and as set forth in **Exhibit 3**, all defendants that are not subject to a bankruptcy stay or injunction and that have been properly joined and served⁸ in this action join in or consent to this removal on the basis of federal question jurisdiction.⁹

⁸ Parties that have not been properly served or properly joined nevertheless consent to the removal in an abundance of caution.

⁹ On September 15, 2019, Purdue Pharma L.P. and its affiliated debtors, including Rhodes Technologies and its affiliates, filed voluntary petitions for relief under chapter 11 of United States Bankruptcy Code in the United States Bankruptcy Court for the Southern District of New York. Purdue Pharma L.P.’s case is docketed as *In re Purdue Pharma L.P.*, No. 19-23649. Also on September 18, 2019, Purdue Pharma L.P. and its affiliated debtors filed a motion for preliminary injunction seeking an order staying certain active cases to the

65. Nothing in this Notice of Removal shall be interpreted as a waiver or relinquishment CVS's or any other defendants' right to assert any and all defenses or objections to the Complaint, including lack of personal jurisdiction.¹⁰ If there are any questions that arise as to the propriety of removal of this action, CVS respectfully requests the opportunity to submit briefing, argument, and additional evidence as necessary to support removal of this case.

Dated: March 11, 2020

Respectfully submitted,



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extent not already stayed by the automatic stay. On June 10, 2019, Insys Therapeutics, Inc. and its affiliates each filed a voluntary case under chapter 11 of United States Bankruptcy Code in the United States Bankruptcy Court for the District of Delaware, which cases are being jointly administered under Case No. 19-11292 (KG). Also on June 10, 2019, Insys filed a motion for preliminary injunction seeking an order staying certain active cases in which Insys had already been served, to the extent not already stayed by the automatic stay. On July 2, 2019, the Bankruptcy Court stayed all actions that were the subject of the preliminary injunction motion, except for actions in which certain plaintiffs resolved the motion with Insys prior to July 2, 2019. On July 9, 2019 the Court in the Delaware County, PA Coordinated Proceedings, Case No. CV-2017-008095, entered an order staying all cases as to Insys within the Coordinated Proceedings, and ordered that such stay would remain in effect pending further order of the Court. As the present case was within the Coordinated Proceedings at the time of removal, the stay as to Insys remains in effect. As bankrupt parties, the consent of Insys, Purdue, and their affiliated debtors is not required. See *Livaccari v. Zack's Famous Frozen Yogurt*, 1992 WL 178734 at *5 (E.D. La. 1992) (“[the defendant’s] bankruptcy and the applicability of the stay order therein eliminate the necessity for [the defendant] to have joined in the notice of removal”); *Consumers Distrib. Co. v. Telesave Merch. Co.*, 553 F. Supp. 974, 975-76 (D.N.J. 1982); *Wallis v. Southern Silo Co.*, 369 F. Supp. 92, 96097 (N.D. Miss. 1973).

¹⁰ CVS also does not concede that it is the properly named CVS entity.

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– and –

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EXHIBIT 1

UNITED STATES JUDICIAL PANEL
on
MULTIDISTRICT LITIGATION

**IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION**

MDL No. 2804

TRANSFER ORDER

Before the Panel:* Plaintiffs in 46 actions move under 28 U.S.C. § 1407 to centralize pretrial proceedings in the Southern District of Ohio or the Southern District of Illinois, but plaintiffs do not oppose centralization in the Southern District of West Virginia. These cases concern the alleged improper marketing of and inappropriate distribution of various prescription opiate medications into cities, states and towns across the country. Plaintiffs' motion includes the 64 actions listed on Schedule A,¹ which are pending in nine districts. Since plaintiffs filed this motion, the parties have notified the Panel of 115 potentially related actions.²

Responding plaintiffs' positions on centralization vary considerably. Plaintiffs in over 40 actions or potential tag-along actions support centralization. Plaintiffs in fifteen actions or potential tag-along actions oppose centralization altogether or oppose transfer of their action. In addition to opposing transfer, the State of West Virginia suggests that we delay transferring its case until the Southern District of West Virginia court decides its motion to remand to state court. Third party payor plaintiffs in an Eastern District of Pennsylvania potential tag-along action (*Philadelphia Teachers Health and Welfare Fund*) oppose centralization of third party payor actions. Western District of Washington plaintiff City of Everett opposes centralization and, alternatively, requests exclusion of its case. Northern District of Illinois tag-along plaintiff City of Chicago asks the Panel to defer transfer of its action until document discovery is completed.

Defendants' positions on centralization also vary considerably. The "Big Three" distributor defendants,³ which reportedly distribute over 80% of the drugs at issue and are defendants in most cases,

* Judges Lewis A. Kaplan and Ellen Segal Huvelle did not participate in the decision of this matter.

¹ Two actions included on plaintiffs' motion to centralize were remanded to state court during the pendency of the motion.

² These actions, and any other related actions, are potential tag-along actions. See Panel Rules 1.1(h), 7.1 and 7.2.

³ AmerisourceBergen Drug Corp., AmerisourceBergen Corp., McKesson Corp., Cardinal Health 110, LLC, Cardinal Health, Inc., Cardinal Health 105, Inc., Cardinal Health 108, LLC, Cardinal Health 112, LLC, Cardinal Health 414, LLC, and Cardinal Health subsidiary The Harvard Drug

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support centralization in the Southern District of West Virginia. These defendants request that the Panel either delay issuing its transfer order or delay transfer of their cases until their motions to dismiss are decided. Defendant distributor Miami-Luken also supports centralization in the Southern District of West Virginia. Multiple manufacturer defendants⁴ support centralization in the Southern District of New York or the Northern District of Illinois; defendant Malinckrodt, LLC, takes no position on centralization but supports the same districts. Teva defendants⁵ suggest centralization in the Eastern District of Pennsylvania or the manufacturers' preferred districts. Physician defendants⁶ in three Ohio actions, who are alleged to be "key opinion leaders" paid by manufacturing defendants, do not oppose centralization in the Southern District of Ohio.

Defendants in several Southern District of West Virginia cases oppose centralization. These defendants include several smaller distributor defendants or "closed" distributors that supply only their own stores.⁷ Many of these defendants specifically request exclusion of the claims against them from the MDL. Also, manufacturer Pfizer, Inc., opposes centralization and requests that we exclude any claims against it from this MDL.⁸

The responding parties suggest a wide range of potential transferee districts, including: the Southern District of West Virginia, the Southern District of Illinois, the Northern District of Illinois, the Eastern District of Missouri (in a brief submitted after the Panel's hearing), the District of New Jersey, the

Group, L.L.C.

⁴ Actavis LLC, Actavis Pharma, Inc., Allergan PLC, Allergan Finance, LLC, Allergan plc f/k/a Actavis plc, Actavis Pharma Inc. f/k/a Watson Pharma Inc., Watson Pharmaceuticals, Inc. n/k/a Actavis, Inc., and Allergan PLC f/k/a Actavis PLS, Cephalon, Inc., Endo Health Solutions, Inc., Endo Pharmaceuticals, Inc., Janssen Pharmaceutica Inc., Johnson & Johnson, Ortho-McNeil-Janssen Pharmaceuticals, Inc., Purdue Frederick Company Inc., Purdue Pharma Inc., Purdue Pharma L.P., Teva Pharmaceuticals Industries Ltd., Teva Pharmaceuticals USA, Inc., Watson Laboratories, Inc., Watson Pharmaceuticals, Inc., Janssen Pharmaceutica Inc. n/k/a Janssen Pharmaceuticals, Inc.

⁵ Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals U.S.A, Inc., Cephalon, Inc., Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc.

⁶ Scott Fishman, M.D., Perry Fine, M.D., Lynn Webster, M.D., and Russell Portenoy, M.D.

⁷ JM Smith Corp.; CVS Indiana, LLC and Omnicare Distribution Center, LLC; TopRx; Kroger Limited Partnership I, Kroger Limited Partnership II, SAJ Distributors (a Walgreens distributor for two months in 2012), Walgreen Eastern Co., Inc., and Rite Aid of Maryland, Inc.; Masters Pharmaceuticals and KeySource Medical; WalMart Stores East, LP.

⁸ Pfizer specifically requests that we exclude any potential future claims against it because of its minimal involvement in the opioid market. At oral argument, counsel stated that Pfizer was not named as a defendant in any pending case. In the absence of a case before us, the Panel will not address Pfizer's argument.

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Southern District of New York, the Southern District of Ohio, the Northern District of Ohio, the Eastern District of Pennsylvania, the Eastern District of Texas, the Western District of Washington and the Eastern District of Wisconsin.

After considering the argument of counsel, we find that the actions in this litigation involve common questions of fact, and that centralization in the Northern District of Ohio will serve the convenience of the parties and witnesses and promote the just and efficient conduct of the litigation. Plaintiffs in the actions before us are cities, counties and states that allege that: (1) manufacturers of prescription opioid medications overstated the benefits and downplayed the risks of the use of their opioids and aggressively marketed (directly and through key opinion leaders) these drugs to physicians, and/or (2) distributors failed to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates. All actions involve common factual questions about, *inter alia*, the manufacturing and distributor defendants' knowledge of and conduct regarding the alleged diversion of these prescription opiates, as well as the manufacturers' alleged improper marketing of such drugs. Both manufacturers and distributors are under an obligation under the Controlled Substances Act and similar state laws to prevent diversion of opiates and other controlled substances into illicit channels. Plaintiffs assert that defendants have failed to adhere to those standards, which caused the diversion of opiates into their communities. Plaintiffs variously bring claims for violation of RICO statutes, consumer protection laws, state analogues to the Controlled Substances Act, as well as common law claims such as public nuisance, negligence, negligent misrepresentation, fraud and unjust enrichment.

The parties opposing transfer stress the uniqueness of the claims they bring (or the claims that are brought against them), and they argue that centralization of so many diverse claims against manufacturers and distributors will lead to inefficiencies that could slow the progress of all cases. While we appreciate these arguments, we are not persuaded by them. All of the actions can be expected to implicate common fact questions as to the allegedly improper marketing and widespread diversion of prescription opiates into states, counties and cities across the nation, and discovery likely will be voluminous. Although individualized factual issues may arise in each action, such issues do not – especially at this early stage of litigation – negate the efficiencies to be gained by centralization. The transferee judge might find it useful, for example, to establish different tracks for the different types of parties or claims. The alternative of allowing the various cases to proceed independently across myriad districts raises a significant risk of inconsistent rulings and inefficient pretrial proceedings. In our opinion, centralization will substantially reduce the risk of duplicative discovery, minimize the possibility of inconsistent pretrial obligations, and prevent conflicting rulings on pretrial motions. Centralization will also allow a single transferee judge to coordinate with numerous cases pending in state courts. Finally, we deny the requests to delay transfer pending rulings on various pretrial motions (*e.g.*, motions to dismiss or to remand to state court) or until the completion of document discovery in *City of Chicago*.

Although all of the cases on the motion before us involve claims brought by political subdivisions, we have been notified of potential tag-along actions brought by individuals, consumers, hospitals and third party payors. As reflected in our questions at oral argument, this litigation might evolve to include

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additional categories of plaintiffs and defendants, as well as different types of claims. We will address whether to include specific actions or claims through the conditional transfer order process.⁹

As this litigation progresses, it may become apparent that certain types of actions or claims could be more efficiently handled in the actions' respective transferor courts. Should the transferee judge deem remand of any claims or actions appropriate (or, relatedly, the subsequent exclusion of similar types of claims or actions from the centralized proceedings), then he may accomplish this by filing a suggestion of remand to the Panel. *See* Panel Rule 10.1. As always, we trust such matters to the sound judgment of the transferee judge.

Most parties acknowledge that any number of the proposed transferee districts would be suitable for this litigation that is nationwide in scope. We are persuaded that the Northern District of Ohio is the appropriate transferee district for this litigation. Ohio has a strong factual connection to this litigation, given that it has experienced a significant rise in the number of opioid-related overdoses in the past several years and expended significant sums in dealing with the effects of the opioid epidemic. The Northern District of Ohio presents a geographically central and accessible forum that is relatively close to defendants' various headquarters in New York, Connecticut, New Jersey and Pennsylvania. Indeed, one of the Big Three distributor defendants, Cardinal Health, is based in Ohio. Judge Dan A. Polster is an experienced transferee judge who presides over several opiate cases. Judge Polster's previous MDL experience, particularly MDL No. 1909 – *In re: Gadolinium Contrast Dyes Products Liability Litigation*, which involved several hundred cases, has provided him valuable insight into the management of complex, multidistrict litigation. We have no doubt that Judge Polster will steer this litigation on a prudent course.

IT IS THEREFORE ORDERED that the actions listed on Schedule A and pending outside of the Northern District of Ohio are transferred to the Northern District of Ohio and, with the consent of that court, assigned to the Honorable Dan A. Polster for coordinated or consolidated pretrial proceedings.

PANEL ON MULTIDISTRICT LITIGATION



Sarah S. Vance
Chair

Charles R. Breyer
R. David Proctor

Marjorie O. Rendell
Catherine D. Perry

⁹ Eastern District of Pennsylvania *Philadelphia Teachers Health and Welfare Fund* third party payor plaintiff opposed centralization of such claims, stating that it intends to file a motion for centralization of third party payor claims. We will address that motion, if it is filed, in due course.

**IN RE: NATIONAL PRESCRIPTION
OPIATE LITIGATION**

MDL No. 2804

SCHEDULE A

Northern District of Alabama

CITY OF BIRMINGHAM v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL.,
C.A. No. 2:17-01360

Eastern District of California

COUNTY OF SAN JOAQUIN, ET AL. v. PURDUE PHARMA, L.P., ET AL.,
C.A. No. 2:17-01485

Southern District of Illinois

PEOPLE OF THE STATE OF ILLINOIS, ET AL. v. PURDUE PHARMA LP, ET AL.,
C.A. No. 3:17-00616

PEOPLE OF THE STATE OF ILLINOIS, ET AL. v. AMERISOURCEBERGEN
DRUG CORPORATION, ET AL., C.A. No. 3:17-00856

PEOPLE OF STATE OF ILLINOIS, ET AL. v. AMERISOURCEBERGEN DRUG
CORPORATION, ET AL., C.A. No. 3:17-00876

Eastern District of Kentucky

BOONE COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG
CORPORATION, ET AL., C.A. No. 2:17-00157

PENDLETON COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG
CORPORATION, ET AL., C.A. No. 2:17-00161

CAMPBELL COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG
CORPORATION, ET AL., C.A. No. 2:17-00167

ANDERSON COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG
CORPORATION, ET AL., C.A. No. 3:17-00070

FRANKLIN COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG
CORPORATION, ET AL., C.A. No. 3:17-00071

SHELBY COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG
CORPORATION, ET AL., C.A. No. 3:17-00072

HENRY COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG
CORPORATION, ET AL., C.A. No. 3:17-00073

BOYLE COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG
CORPORATION, ET AL., C.A. No. 5:17-00367

FLEMING COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG
CORPORATION, ET AL., C.A. No. 5:17-00368

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Eastern District of Kentucky (cont.)

GARRARD COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 5:17-00369
LINCOLN COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 5:17-00370
MADISON COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 5:17-00371
NICHOLAS COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 5:17-00373
BELL COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 6:17-00246
HARLAN COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 6:17-00247
KNOX COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 6:17-00248
LESLIE COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 6:17-00249
WHITLEY COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 6:17-00250
CLAY COUNTY FISCAL COURT v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 6:17-00255

Western District of Kentucky

THE FISCAL COURT OF CUMBERLAND COUNTY v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 1:17-00163
LOUISVILLE/JEFFERSON COUNTY METRO GOVERNMENT v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 3:17-00508
THE FISCAL COURT OF SPENCER COUNTY v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 3:17-00557
THE FISCAL COURT OF UNION COUNTY v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 4:17-00120
THE FISCAL COURT OF CARLISLE COUNTY v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 5:17-00136

Northern District of Ohio

CITY OF LORAIN v. PURDUE PHARMA L.P., ET AL., C.A. No. 1:17-01639
CITY OF PARMA v. PURDUE PHARMA L.P., ET AL., C.A. No. 1:17-01872

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Southern District of Ohio

CLERMONT COUNTY BOARD OF COUNTY COMMISSIONERS v.
AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 2:17-00662
BELMONT COUNTY BOARD OF COUNTY COMMISSIONERS v.
AMERISOURCEBERGEN DRUG CORPORATION, ET AL., C.A. No. 2:17-00663
BROWN COUNTY BOARD OF COUNTY COMMISSIONERS v. AMERISOURCEBERGEN
DRUG CORPORATION, ET AL., C.A. No. 2:17-00664
VINTON COUNTY BOARD OF COUNTY COMMISSIONERS v. AMERISOURCEBERGEN
CORPORATION, ET AL., C.A. No. 2:17-00665
JACKSON COUNTY BOARD OF COUNTY COMMISSIONERS v. AMERISOURCEBERGEN
DRUG CORPORATION, ET AL., C.A. No. 2:17-00680
SCIOTO COUNTY BOARD OF COUNTY COMMISSIONERS v. AMERISOURCEBERGEN
DRUG CORPORATION, ET AL., C.A. No. 2:17-00682
PIKE COUNTY BOARD OF COUNTY COMMISSIONERS v. AMERISOURCEBERGEN
DRUG CORPORATION, ET AL., C.A. No. 2:17-00696
ROSS COUNTY BOARD OF COUNTY COMMISSIONERS v. AMERISOURCEBERGEN
DRUG CORPORATION, ET AL., C.A. No. 2:17-00704
CITY OF CINCINNATI v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL.,
C.A. No. 2:17-00713
CITY OF PORTSMOUTH v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL.,
C.A. No. 2:17-00723
GALLIA COUNTY BOARD OF COMMISSIONERS v. AMERISOURCEBERGEN DRUG
CORPORATION, ET AL., C.A. No. 2:17-00768
HOCKING COUNTY BOARD OF COMMISSIONERS v. AMERISOURCEBERGEN DRUG
CORPORATION, ET AL., C.A. No. 2:17-00769
LAWRENCE COUNTY BOARD OF COMMISSIONERS v. AMERISOURCEBERGEN DRUG
CORPORATION, ET AL., C.A. No. 2:17-00770
DAYTON v. PURDUE PHARMA LP, ET AL., C.A. No. 3:17-00229

Western District of Washington

CITY OF EVERETT v. PURDUE PHARMA LP, ET AL., C.A. No. 2:17-00209
CITY OF TACOMA v. PURDUE PHARMA, L.P., ET AL., C.A. No. 3:17-05737

Southern District of West Virginia

THE COUNTY COMMISSION OF MCDOWELL COUNTY v. MCKESSON CORPORATION,
ET AL., C.A. No. 1:17-00946
HONAKER v. WEST VIRGINIA BOARD OF PHARMACY, ET AL., C.A. No. 1:17-03364
THE COUNTY COMMISSION OF MERCER COUNTY v. WEST VIRGINIA BOARD OF
PHARMACY, C.A. No. 1:17-03716

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Southern District of West Virginia (cont.)

KANAWHA COUNTY COMMISSION v. RITE AID OF MARYLAND, INC., ET AL.,
C.A. No. 2:17-01666
FAYETTE COUNTY COMMISSION v. CARDINAL HEALTH, INC., ET AL.,
C.A. No. 2:17-01957
BOONE COUNTY COMMISSION v. AMERISOURCEBERGEN DRUG CORPORATION,
ET AL., C.A. No. 2:17-02028
LOGAN COUNTY COMMISSION v. CARDINAL HEALTH, INC., ET AL.,
C.A. No. 2:17-02296
THE COUNTY COMMISSION OF LINCOLN COUNTY v. WEST VIRGINIA BOARD OF
PHARMACY, ET AL., C.A. No. 2:17-03366
LIVINGGOOD v. WEST VIRGINIA BOARD OF PHARMACY, ET AL., C.A. No. 2:17-03369
SPARKS v. WEST VIRGINIA BOARD OF PHARMACY, C.A. No. 2:17-03372
CARLTON, ET AL. v. WEST VIRGINIA BOARD OF PHARMACY, ET AL.,
C.A. No. 2:17-03532
STATE OF WEST VIRGINIA, ET AL. v. MCKESSON CORPORATION, C.A. No. 2:17-03555
BARKER v. WEST VIRGINIA BOARD OF PHARMACY, ET AL., C.A. No. 2:17-03715
THE CITY OF HUNTINGTON v. AMERISOURCEBERGEN DRUG CORPORATION, ET AL.,
C.A. No. 3:17-01362
CABELL COUNTY COMMISSION v. AMERISOURCEBERGEN DRUG CORPORATION, ET
AL., C.A. No. 3:17-01665
WAYNE COUNTY COMMISSION v. RITE AID OF MARYLAND, INC., ET AL.,
C.A. No. 3:17-01962
WYOMING COUNTY COMMISSION v. AMERISOURCEBERGEN DRUG
CORPORATION, ET AL., C.A. No. 5:17-02311

EXHIBIT 2

Case No..... 2020-00180 BEDFORD COUNTY (vs) PURDUE PHARMA L P ETAL

Reference No.....
Case Type..... TORT - PRODUCT LIABILITY
Judgment..... \$.00
Judge Assigned.... LIVENGOD TRAVIS W
Disposed Desc.....
----- Case Comments -----

Filed..... 2/11/2020
Time..... 1:38
Execution Date.. 0/00/0000
Jury Trial.....
Disposed Date.. 0/00/0000
Higher Crt 1...
Higher Crt 2...

++ GENERAL INDEX ++

Indexed Party

BEDFORD COUNTY
BEDFORD, PA 15522

PLAINTIFF

Attorney Info

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CONSHOHOCKEN, PA 19428
SCATTON BARRY J
101 WEST ELM STREET SUITE 215
CONSHOHOCKEN, PA 19428

PURDUE PHARMA L P
STAMFORD, CT 06901

DEFENDANT

PURDUE PHARMA INC
STAMFORD, CT 06901

DEFENDANT

THE PURDUE FREDERICK COMPANY
INC
STAMFORD, CT 06901

DEFENDANT

TEVA PHARMACEUTICALS USA INC
NORTH WALES, PA 19454

DEFENDANT

CEPHALON INC
NORTH WALES, PA 19454

DEFENDANT

JOHNSON & JOHNSON
NEW BRUNSWICK, NJ 08933

DEFENDANT

JANSSEN PHARMACEUTICALS INC
TITUSVILLE, NJ 08560-0200

DEFENDANT

NORAMCO INC
WILMINGTON, DE 19801

DEFENDANT

ORTHO-MCNEIL-JANSSEN
PHARMACEUTICALS INC N/K/A
TITUSVILLE, NJ 08560-0200

DEFENDANT

JANSSEN PHARMACEUTICALS INC
TITUSVILLE, NJ 08560-0200

DEFENDANT

JANSSEN PHARMACEUTICA INC
N/K/A
TITUSVILLE, NJ 08560-0200

DEFENDANT

JANSSEN PHARMACEUTICALS INC
TITUSVILLE, NJ 08560-0200

DEFENDANT

ENDO HEALTH SOLUTIONS INC
MALVERN, PA 19355

DEFENDANT

ENDO PHARMACEUTICALS INC
MALVERN, PA 19355

DEFENDANT

MCKESSON CORPORATION
SAN FRANCISCO, CA 94104

DEFENDANT

CARDINAL HEALTH INC
DUBLIN, OH 43017

DEFENDANT

RASPANTI MARC
1818 MARKET ST SUITE 3402
PHILADELPHIA, PA 19103
ROSENBLUM DOUGLAS
1818 MARKET ST SUITE 3402
PHILADELPHIA, PA 19103

Case No..... 2020-00180 BEDFORD COUNTY (vs) PURDUE PHARMA L P ETAL

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Higher Crt 2...

SACKLER RICHARD S AUSTIN, TX 78746-3216	DEFENDANT
SACKLER JONATHAN D STAMFORD, CT 06901-3435	DEFENDANT
SACKLER MORTIMER D A NEW YORK, NY 10021-2609	DEFENDANT
SACKLER KATHE A WESTON, CT 06833-2600	DEFENDANT
LEFCOURT ILENE SACKLER NEW YORK, NY 10023-7092	DEFENDANT
SACKLER VEVERLY GREENWICH, CT 06830-7011	DEFENDANT
SACKLER THERESA NEW YORK, NY 10075-0126	DEFENDANT
SACKLER DAVID A NEW YORK, NY 10065-9175	DEFENDANT
RHODES TECHNOLOGIES WARWICK, RI 02888	DEFENDANT
RHODES TECHNOLOGIES INC WARWICK, RI 02888	DEFENDANT
RHODES PHARMACEUTICALS L P WARWICK, RI 02888	DEFENDANT
RHODES PHARMACEUTICALS INC WARWICK, RI 02888	DEFENDANT
TRUST FOR THE BENEFIT OF MEMBERS OF THE RAYMOND SACKLER AUSTIN, TX 78746-3216	DEFENDANT
THE P F LABORATORIES INC TOTOWA, NJ 07512	DEFENDANT
BAKER STUART D NEW YORK, NY 10022	DEFENDANT
ALLERGAN PLC F/K/A WILMINGTON, DE 19801	DEFENDANT
ACTAVIS PLC WILMINGTON, DE 19801	DEFENDANT
WATSON PHARMACEUTICALS INC N/K/A WILMINGTON, DE 19810	DEFENDANT
ACTAVIS INC WILMINGTON, DE 19810	DEFENDANT
WATSON LABORATORIES INC WILMINGTON, DE 19810	DEFENDANT
ACTAVIS LLC WILMINGTON, DE 19810	DEFENDANT

Case No..... 2020-00180 BEDFORD COUNTY (vs) PURDUE PHARMA L P ETAL

Reference No.....
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Higher Crt 2...

ACTAVIS PHARMA INC F/K/A WILMINGTON, DE 19810	DEFENDANT
WATSON PHARMA INC WILMINGTON, DE 19810	DEFENDANT
PAR PHARMACEUTICAL INC CHESTNUT RIDGE, NY 10977	DEFENDANT
PAR PHARMACEUTICALS COMPANIES INC CHESTNUT RIDGE, NY 10977	DEFENDANT
MALLINCKRODT PLC CLAYTON, MO 63105	DEFENDANT
MALLINCKRODT LLC CLAYTON, MO 63105	DEFENDANT
SPECGX LLC PLANTATION, FL 33324	DEFENDANT
ANDA INC PALM BEACH GARDENS, FL 33410	DEFENDANT
CVS HEALTH CORPORATION WOONSOCKET, PI 02895	DEFENDANT
RITE AID OF MARYLAND INC DBA WILMINGTON, DE 19801	DEFENDANT
RITE AID MID-ATLANTIC CUSTOMER SUPPORT CENTER INC WILMINGTON, DE 19801	DEFENDANT
RITE AID CORPORATION WILMINGTON, DE 19801	DEFENDANT
WAL-MART INC WILMINGTON, DE 19801	DEFENDANT
INSYS THERAPEUTICS INC WILMINGTON, DE 19801	DEFENDANT
AMNEAL PHARMACEUTICALS LLC WILMINGTON, DE 19801	DEFENDANT
ECKERD CORPORATION WILMINGTON, DE 19801	DEFENDANT
ROCHESTER DRUG CO-OPERATIVE INC ROCHESTER, NY 14624	DEFENDANT
VALUE DRUG DUNCANSVILLE, PA 00166	DEFENDANT

++ DOCKET ENTRIES ++

Date	Entry Text
2/11/2020	FIRST ENTRY COMPLAINT - TORT - PRODUCT LIABILITY FIED BY JOSEPH J CAPPELLI AND BARRY SCATTON ESQ.

Case No..... 2020-00180 BEDFORD COUNTY (vs) PURDUE PHARMA L P ETAL

Reference No.....		Filed.....	2/11/2020
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		Higher Crt 2...	

288 Image page(s) exists for this entry

3/04/2020 PRAECIPE FOR ENTRY OF APPEARANCE FILED WITH CERTIFICATE OF SERVICE
FILED BY DOUGLAS K ROSENBLUM

2 Image page(s) exists for this entry

3/04/2020 PRAECIPE FOR ENTRY OF APPEARANCE FILED WITH CERTIFICATE OF SERVICE
FILED BY MARC S RASPANTI

2 Image page(s) exists for this entry

- - - - - LAST ENTRY - - - - -

++ Escrow Information ++

<u>Cost / Fee</u>	<u>Beg. Balance</u>	<u>Pymts/Adjmts</u>	<u>End. Balance</u>
TAX ON CMPLT	\$.50	\$.50	\$.00
JCP FEE	\$40.25	\$40.25	\$.00
AUTO. FEE	\$5.00	\$5.00	\$.00
COMPLAINT FILED	\$83.25	\$83.25	\$.00
	-----	-----	-----
	\$129.00	\$129.00	\$.00

End of Case Information

IN THE COURT OF COMMON PLEAS OF DELAWARE COUNTY, PENNSYLVANIA

DELAWARE COUNTY, PENNSYLVANIA,

Plaintiff,

v.

PURDUE PHARMA L.P., *et al.*,

Defendants.

:
: No: 2017-008095
:
:
: Coordinated Civil Actions
:
:
:
:
:
:

NOTICE OF RECENTLY-FILED CASES FOR COORDINATION

Pursuant to this Court's March 26, 2018, June 13, 2018, September 14, 2018, and September 27, 2018 Orders (attached hereto and collectively "the Orders"), the undersigned Defendants hereby give notice that the following action presents common questions of law or fact with those in this coordinated proceeding:

Bedford County, Pennsylvania v. Purdue Pharma L.P., et al. (Bedford County CCP, No. 180-2020)

As set forth in the attached September 27, 2018 Order of this Court, the parties in this case have fourteen days from the date of this notice to object to being part of the coordinated proceeding. If no objection is filed, the case will be deemed part of the coordinated proceeding. Any objection should be filed in accordance with the September 27 Order. Pursuant to the Orders, this case is stayed pending resolution of any objections to being part of the coordinated proceeding.

Dated: February 25, 2020

Respectfully submitted,

IMPERATRICE, AMARANT & BELL, P.C.

By: /s/ Rocco P. Imperatrice, III

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*Counsel for Defendants Endo Health
Solutions Inc. and Endo Pharmaceuticals Inc.*

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Tel: (610) 353-0740
Fax: (610) 353-0745

Counsel for Defendants
Endo Pharmaceuticals, Inc. and
Endo Health Solutions, Inc.

DELAWARE COUNTY, PENNSYLVANIA	:	COURT OF COMMON PLEAS
	:	DELAWARE COUNTY, PA
Plaintiff,	:	
v.	:	NO. CV-2017-008095
	:	
PURDUE PHARMA, L.P., et al.	:	Coordinated Civil Actions Docket
	:	
Defendants.	:	

CERTIFICATE OF SERVICE

I hereby certify that I am this day serving the foregoing Notice of Recently-Filed Cases for Coordination upon the following interested parties via electronic mail as indicated on the attached Service List.

IMPERATRICE, AMARANT & BELL, P.C.

BY: /s/ Rocco P. Imperatrice, III
ROCCO P. IMPERATRICE, III, ESQUIRE
3405 West Chester Pike
Newtown Square, PA 19073
(610) 353-0740
rimperatrice@iablegal.com
Counsel for Defendants Endo Pharmaceuticals,
Inc. and Endo Health Solutions, Inc.

Dated: February 25, 2020

SERVICE LIST*

Plaintiffs' Counsel	Case
<p>Carmen P. Belefonte, Esq. Saltz Mongeluzzi Barrett & Bendesky 20 West Third St. Media, PA 19063 cbelefonte@smbb.com</p>	<p><i>Delaware County, PA v. Purdue Pharma, LP, et al.</i> (Delaware County CCP, No. 2017-008095)</p> <p><i>Schuylkill County v. Purdue Pharma L.P., et al.</i> (Schuylkill Co. CCP, No. S-1241-18)</p> <p><i>Tioga County v. Purdue Pharma, L.P., et al.</i> (Tioga Co. CCP, No. 563-CV-2018)</p>
<p>Harris L. Pogust, Esq. Tobias L. Millrood, Esq. Gabriel C. Magee, Esq. Pogust Millrood, LLC 161 Washington St., Suite 940 Conshohocken, PA 19428 hpogust@pbmattorneys.com Tmillrood@pogustmillrood.com gmagee@pogustmillrood.com</p>	<p><i>Delaware County, PA v. Purdue Pharma, LP, et al.</i> (Delaware County CCP, No. 2017-008095)</p> <p><i>Schuylkill County v. Purdue Pharma L.P., et al.</i> (Schuylkill Co. CCP, No. S-1241-18)</p> <p><i>AFSCME District Council 47 Health and Welfare Fund v. Purdue Pharma, L.P., et al.</i> (Philadelphia CCP, No. 180302255)</p> <p><i>AFSCME District Council 33 Health and Welfare Fund v. Purdue Pharma, L.P., et al.</i> (Philadelphia CCP, No. 18030256)</p> <p><i>Bricklayers and Allied Craftworkers Local Union No. 1 of PA/DE Health and Welfare v. Purdue Pharma, L.P., et al.</i> (Philadelphia CCP, No. 180302256)</p> <p><i>Carpenters Health & Welfare of Philadelphia & Vicinity v. Purdue Pharma, L.P., et al.</i> (Philadelphia CCP, No. 180302264)</p> <p><i>The Trustees of the Unite Here Local 634 Health and Welfare v. Purdue Pharma, L.P., et al.</i> (Philadelphia CCP, No. 18040112)</p>

* denotes counsel whose applications for pro hac vice admission are pending or will be forthcoming in one or more of the coordinated actions.

Plaintiffs' Counsel	Case
<p>Paul J. Hanly, Jr., Esq. Jayne Conroy, Esq.* Andrea Bierstein, Esq.* Simmons Hanly Conroy LLC 112 Madison Avenue New York, NY 10016 phanly@simmonsfirm.com ABierstein@simmonsfirm.com</p> <p>Amy E. Garrett, Esq.* Trent B. Miracle, Esq.* Sarah Burns, Esq. Rick Kroeger, Esq.* Simmons Hanly Conroy LLC One Court Street Alton, IL 62002 tmiracle@simmonsfirm.com sburns@simmonsfirm.com</p>	<p><i>Delaware County, PA v. Purdue Pharma, LP, et al.</i> (Delaware County CCP, No. 2017-008095)</p> <p><i>Dauphin County, PA v. Purdue Pharma, LP, et al.</i> (Dauphin County CCP, No. 2018-CV-716)</p> <p><i>Pike County v. Purdue Pharma L.P., et al.</i> (Pike County CCP, No. 602-2018)</p> <p><i>Schuylkill County v. Purdue Pharma L.P., et al.</i> (Schuylkill Co. CCP, No. S-1241-18)</p> <p><i>AFSCME District Council 47 Health and Welfare Fund v. Purdue Pharma, L.P., et al.</i> (Phila. CCP, No. 180302255)</p> <p><i>AFSCME District Council 33 Health and Welfare Fund v. Purdue Pharma, L.P., et al.</i> (Phila. CCP, No. 180302256)</p> <p><i>Bricklayers and Allied Craftworkers Local Union No. 1 of PA/DE Health and Welfare v. Purdue Pharma, L.P., et al.</i> (Phila. CCP, No. 180302256)</p> <p><i>Carpenters Health & Welfare of Philadelphia & Vicinity v. Purdue Pharma, L.P., et al.</i> (Phila. CCP, No. 180302264)</p> <p><i>The Trustees of the Unite Here Local 634 Health and Welfare v. Purdue Pharma, L.P., et al.</i> (Phila. CCP, No. 18040112)</p> <p><i>Tioga County v. Purdue Pharma, L.P., et al.</i> (Tioga Co. CCP, No. 563-CV-2018)</p>
<p>Daniel Schwarz, Esq. Schwarz Mongeluzzi Law, LLP One Liberty Place 1650 Market Street, 51st Floor Philadelphia, PA 19103 dschwarz@sm-attorneys.com</p>	<p><i>Delaware County, PA v. Purdue Pharma, LP, et al.</i> (Delaware County CCP, No. 2017-008095)</p> <p><i>AFSCME District Council 47 Health and Welfare Fund v. Purdue Pharma, L.P., et al.</i> (Phila. CCP, No. 180302255)</p> <p><i>AFSCME District Council 33 Health and Welfare Fund v. Purdue Pharma, L.P., et al.</i> (Phila. CCP, No. 180302256)</p> <p><i>Bricklayers and Allied Craftworkers Local Union No. 1 of PA/DE Health and Welfare v. Purdue Pharma, L.P., et al.</i> (Phila. CCP, No. 180302256)</p> <p><i>Carpenters Health & Welfare of Philadelphia & Vicinity v. Purdue Pharma, L.P., et al.</i> (Phila. CCP, No. 180302264)</p> <p><i>The Trustees of the Unite Here Local 634 Health and Welfare v. Purdue Pharma, L.P., et al.</i> (Phila. CCP, No. 18040112)</p> <p><i>Tioga County v. Purdue Pharma, L.P., et al.</i> (Tioga Co. CCP, No. 563-CV-2018)</p>

Plaintiffs' Counsel	Case
<p>Deborah R. Willig, Esq. Willig, Williams & Davidson 1845 Walnut Street, 24th Fl. Philadelphia, PA 19103 dwillig@wwdlaw.com</p>	<p><i>AFSCME District Council 47 Health and Welfare Fund v. Purdue Pharma, L.P., et al.</i> (Philadelphia CCP, No. 180302255)</p> <p><i>The Trustees of the Unite Here Local 634 Health and Welfare v. Purdue Pharma, L.P., et al.</i> (Philadelphia CCP, No. 18040112)</p>
<p>Joseph J. Cappelli, Esq. Barry J. Scatton, Esq. Thomas J. Joyce, Esq. Marc J. Bern & Partners LLP 101 West Elm Street, Suite 215 Conshohocken, PA 19428 jcappelli@bernllp.com bscatton@bernllp.com tjoyce@bernllp.com</p>	<p><i>Armstrong County v. Purdue Pharma, LP, et al.</i> (No. 2017-1570)</p> <p><i>Beaver County v. Purdue Pharma, LP, et al.</i> (No. 11326-2017)</p> <p><i>Cambria County v. Purdue Pharma, LP, et al.</i> (No. 2017-4131)</p> <p><i>Greene County v. Purdue Pharma, LP, et al.</i> (No. 791-2017)</p> <p><i>Fayette County v. Purdue Pharma, LP, et al.</i> (2017-2676)</p> <p><i>Lackawanna County, PA v. Purdue Pharma, LP, et al.</i> (No. 2017-05156)</p> <p><i>Lawrence County v. Purdue Pharma, LP, et al.</i> (No. 11180-2017)</p> <p><i>Washington County, PA v. Purdue Pharma, LP, et al.</i> (No. C-63-CV-2017-6268)</p> <p><i>Westmoreland County v. Purdue Pharma, LP, et al.</i> (No. 2017-5975)</p> <p><i>County of Clarion v. Purdue Pharma, LP, et al.</i> (No. 2018-CV-0059)</p> <p><i>County of Bradford v. Purdue Pharma, LP, et al.</i> (No. 2018-CV-0059)</p> <p><i>County of Carbon v. Purdue Pharma, LP, et al.</i> (No. 18-0990)</p> <p><i>County of Lehigh v. Purdue Pharma, LP, et al.</i> (No. 2018-C-0716)</p> <p><i>Township of Bensalem v. Purdue Pharma, L.P., et al.</i> (Bucks County CCP, No. 2018-03199)</p> <p><i>County of Monroe v. Purdue Pharma, L.P., et al.</i> (No. 3972-CV-18)</p> <p><i>Huntingdon County v. Purdue Pharma L.P., et al.</i> (Huntingdon County CCP, No. 2018-00784)</p>

Plaintiffs' Counsel	Case
<p>Todd O'Malley, Esq. O'Malley & Langan Law Offices 201 Franklin Ave. Scranton, PA 18503 tomalley@omalleylangan.com</p>	<p><i>Lackawanna County, PA v. Purdue Pharma, LP, et al.</i> (No. 2017-05156)</p>
<p>Daniel A. Miscavige, Esq. Carbon County Solicitor 2 Hazard Square P.O. Box 129 Jim Thorpe, PA 18229 dam@gmlawoffices.com</p>	<p><i>County of Carbon v. Purdue Pharma, LP, et al.</i> (No. 18-0990)</p>
<p>John Brazil, Esq. Lackawanna County Solicitor 200 Adams Ave., 6th Floor Scranton, PA 18503 jbrazilcounty@gmail.com</p>	<p><i>Lackawanna County, PA v. Purdue Pharma, LP, et al.</i> (No. 2017-05156)</p>
<p>Robert N. Peirce, Jr., Esq. Robert Peirce & Associates, P.C. 707 Grant Street, Suite 2500 Pittsburgh, PA 15219 rpeircejr@peircelaw.com</p>	<p><i>Armstrong County v. Purdue Pharma, LP, et al.</i> (No. 2017-1570)</p> <p><i>Beaver County v. Purdue Pharma, LP, et al.</i> (No. 11326-2017)</p> <p><i>Cambria County v. Purdue Pharma, LP, et al.</i> (No. 2017-4131)</p> <p><i>Greene County v. Purdue Pharma, LP, et al.</i> (No. 791-2017)</p> <p><i>Fayette County v. Purdue Pharma, LP, et al.</i> (2017-2676)</p> <p><i>Lackawanna County, PA v. Purdue Pharma, LP, et al.</i> (No. 2017-05156)</p> <p><i>Lawrence County v. Purdue Pharma, LP, et al.</i> (No. 11180-2017)</p> <p><i>Washington County, PA v. Purdue Pharma, LP, et al.</i> (No. C-63-CV-2017-6268)</p> <p><i>Westmoreland County v. Purdue Pharma, LP, et al.</i> (No. 2017-5975)</p> <p><i>County of Clarion v. Purdue Pharma, LP, et al.</i> (No. 2018-CV-0059)</p>

Plaintiffs' Counsel	Case
<p>Andrew J. Sacco, Esq. Armstrong County Solicitor 160 N. McKean Street Kittanning, PA 16201 sslaw@windstream.net</p>	<p><i>Armstrong County v. Purdue Pharma, LP, et al.</i> (No. 2017-1570)</p>
<p>Glenn J. Smith, Esq. Michelle Pokrifka, Esq. York County Solicitor York County Administration Center 28 East Market St., 2nd Floor York, PA 17401 gsmith@yorkcountypa.gov mpokrifka@yorkcountypa.gov</p>	<p><i>County of York v. Purdue Pharma</i> (No. 2017-SU-003372)</p>
<p>Hunter J. Shkolnik, Esq. Napoli Shkolnik PLLC 360 Lexington Avenue, 11th Floor New York, NY 10017 Hunter@napolilaw.com</p> <p>Joseph L. Ciaccio, Esq. Shayna E. Sacks, Esq. Salvatore C. Badala, Esq. Napoli Shkolnik, PLLC 400 Broadhollow Road, Suite 305 Melville, NY 11747 ssacks@napolilaw.com JCiaccio@napolilaw.com sbadala@napolilaw.com</p> <p>W. Steven Berman, Esq. Napoli Shkolnik, PLLC 1 Greentree Centre, Suite 201 10,000 Lincoln Drive East Marlton, NJ 08053 wsberman@napolilaw.com</p>	<p><i>County of York v. Purdue Pharma</i> (No. 2017-SU-003372)</p> <p><i>County of Cumberland v. Purdue Pharma Inc.</i> (No. 2018-02147)</p>
<p>John M. Purcell, Esq. Fayette County Solicitor 61 East Main Street Uniontown, PA 15401 Jackpurcell146@gmail.com</p>	<p><i>Fayette County v. Purdue Pharma, LP, et al.</i> (2017-2676)</p>

Plaintiffs' Counsel	Case
<p>Brian J. Taylor, Esq. Office of Northampton County Solicitor 669 Washington Street Easton, PA 18042 btaylor@kingspry.com</p>	<p><i>County of Northampton v. Purdue Pharma, et al.</i> (No. C-48-cv-2017-11557)</p>
<p>Christian M. Perrucci, Esq. Robert M. Donchez, Esq. Robert A. Freedberg, Esq. Florio Perrucci Steinhardt & Cappelli, LLC 60 West Broad Street Suite 102 Bethlehem, PA 18018 CPerrucci@floriolaw.com RDonchez@floriolaw.com RFreedberg@floriolaw.com</p>	<p><i>County of Northampton v. Purdue Pharma, et al.</i> (No. C-48-cv-2017-11557)</p>
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<p>Donald E. Haviland, Jr., Esq. William H. Platt II, Esq. Christina M. Philipp, Esq. Haviland Hughes 201 S. Maple Way, Suite 110 Ambler, PA 19002 haviland@havilandhughes.com platt@havilandhughes.com philipp@havilandhughes.com</p>	<p><i>County of Lehigh v. Purdue Pharma, LP, et al.</i> (No. 2018-C-0716)</p>
<p>Hugh Donaghue, Esq. Kathryn Labrum, Esq. Tyler J. Therriault, Esq. Donaghue & Labrum, LLP 104 W. Front Street Suite 201 Media, PA 19063 info@donaghuelabrum.com kathy@donaghuelabrum.com tyler@donaghuelabrum.com</p>	<p><i>County of Lehigh v. Purdue Pharma, LP, et al.</i> (No. 2018-C-0716)</p>

Plaintiffs' Counsel	Case
<p>Marcel S. Pratt, Chair, Litigation Group Eleanor N. Ewing, Chief Deputy Solicitor Benjamin H. Field, Deputy City Solicitor City of Philadelphia Law Department 1515 Arch Street, 17th Floor Philadelphia, PA 19102 marcel.pratt@phila.gov eleanor.ewing@phila.gov benjamin.field@phila.gov</p>	<p><i>City of Phila. v. Allergan PLC, et al.</i> (Philadelphia CCP, No. 180102718)</p>
<p>Lawrence S. Krasner, Esq., Phila. District Attorney Nancy Winkelman, Esq. Office of the District Attorney of Philadelphia 3 S. Penn Square, 13th Floor Philadelphia, PA 19107 nancy.winkelman@phila.gov</p>	<p><i>Commonwealth of PA, et al., v. Purdue Pharma L.P., et al.</i> (Philadelphia CCP, No. 180105594)</p>
<p>Jerry R. DeSiderato, Esq. Thomas S. Biemer, Esq. Dilworth Paxson, LLP 1500 Market St., Suite 3500E Philadelphia, PA 19102 jdesiderato@dilworthlaw.com tbiemer@dilworthlaw.com</p>	<p><i>City of Phila. v. Allergan PLC, et al.</i> (Philadelphia CCP, No. 180102718)</p> <p><i>Commonwealth of PA, et al., v. Purdue Pharma L.P., et al.</i> (Philadelphia CCP, No. 180105594)</p>
<p>Andrew Sacks, Esq. John Weston, Esq. Sacks Weston Diamond, LLC 1845 Walnut Street, Suite 1600 Philadelphia, PA 19103 asacks@sackslaw.com jweston@sackslaw.com</p>	<p><i>City of Phila. v. Allergan PLC, et al.</i> (Philadelphia CCP, No. 180102718)</p> <p><i>Commonwealth of PA, et al., v. Purdue Pharma L.P., et al.</i> (Philadelphia CCP, No. 180105594)</p>
<p>Stephen A. Sheller, Esq. Lauren Sheller, Esq. Jamie Sheller, Esq. Sheller, P.C. 1528 Walnut Street, 4th Floor Philadelphia, PA 19102 sasheller@sheller.com lsheller@sheller.com jsheller@sheller.com</p>	<p><i>City of Phila. v. Allergan PLC, et al.</i> (Philadelphia CCP, No. 180102718)</p> <p><i>Commonwealth of PA, et al., v. Purdue Pharma L.P., et al.</i> (Philadelphia CCP, No. 180105594)</p>

Plaintiffs' Counsel	Case
<p>Gregory B. Heller, Esq. Young Ricchiuti Caldwell & Heller, LLC 1600 Market Street, Suite 1650 Philadelphia, PA 19103 gheller@yrchl.com</p>	<p><i>Dauphin County, PA v. Purdue Pharma, LP, et al.</i> (Dauphin County CCP, No. 2018-CV-716)</p> <p><i>City of Phila. v. Allergan PLC, et al.</i> (Philadelphia CCP, No. 180102718)</p> <p><i>Commonwealth of PA, et al., v. Purdue Pharma L.P., et al.</i> (Philadelphia CCP, No. 180105594)</p> <p><i>Township of Bensalem v. Purdue Pharma, L.P., et al.</i> (Bucks County CCP, No. 2018-03199)</p> <p><i>Pike County v. Purdue Pharma L.P., et al.</i> (Pike County CCP, No. 602-2018)</p>
<p>David Kairys, Esq. PO Box 4073 8225 Germantown Avenue Philadelphia, PA 19118 dkairys@verizon.net</p>	<p><i>City of Phila. v. Allergan PLC, et al.</i> (Philadelphia CCP, No. 180102718)</p> <p><i>Commonwealth of PA, et al., v. Purdue Pharma L.P., et al.</i> (Philadelphia CCP, No. 180105594)</p>
<p>Sol H. Weiss, Esq. Gregory S. Spizer, Esq. Anapol Weiss One Logan Square 130 N. 18th Street, Suite 1600 Philadelphia, PA 19103 sweiss@anapolweiss.com gspizer@anapolweiss.com</p>	<p><i>Southeastern Pennsylvania Transportation Authority v. Endo Pharmaceuticals, Inc., et al.</i> (Philadelphia CCP, No. 180302923)</p> <p><i>UFCW, Local 23 and Employers Health Fund v. Endo Pharmaceuticals, Inc., et al.</i> (Philadelphia CCP, No. 180403485)</p> <p><i>Philadelphia Federation of Teachers Health and Welfare Fund v. Endo Pharmaceuticals, Inc., et al.</i> (Philadelphia CCP, No. 180403891)</p> <p><i>Iron Workers District Council of Philadelphia and Vicinity, Benefit Fund v. Abbott Laboratories, Inc., et al.</i> (Philadelphia CCP, No. 180502442)</p> <p><i>Western PA Electrical Employees Insurance Trust Fund v. Endo Pharmaceuticals, Inc., et al.</i> (Phila. CCP No. 181002038)</p>
<p>David S. Senoff, Esq. Hillary Weinstein, Esq. First Law Strategy Group, LLC 121 S. Broad Street, Suite 300 Philadelphia, PA 19107 dsenoff@firstlawstrategy.com</p>	

Plaintiffs' Counsel	Case
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<p>Jay Edelson, Esq.* Rafey S. Balabanian, Esq.* Benjamin H. Richman, Esq.* Edelson PC 350 North LaSalle Street, 14th Floor Chicago, IL 60654 jedelson@edelson.com rbalabanian@edelson.com brichman@edelson.com</p>	<p><i>Southeastern Pennsylvania Transportation Authority v. Endo Pharmaceuticals, Inc., et al.</i> (Philadelphia CCP, No. 180302923)</p>
<p>Andrew F. Szefi, Esq. Allegheny County Law Department 445 Fort Pitt Boulevard Suite 300 Pittsburgh, PA 15219 andrew.szefi@alleghenycounty.us</p>	<p><i>County of Allegheny v. Purdue Pharma L.P., et al.</i> (Allegheny County CCP No. 006155)</p>
<p>Yvonne Hilton, Esq. Julie Koren, Esq. City of Pittsburgh 414 Grant Street, Third Floor Pittsburgh, PA 15219 yvonne.hilton@pittsburghpa.gov</p>	<p><i>City of Pittsburgh v. Purdue Pharma L.P., et al.</i> (Allegheny County CCP, No. GD-18-006153)</p>
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<p>Charles R. Rosamilia, Jr., Esq. R. Thom Rosamilia, Esq. Rosamilia, Brungard & Rosamilia 241 West Main Street Lock Haven, PA 17745 thom@rosamilialaw.com</p>	<p><i>Clinton County v. Purdue Pharma L.P., et al.</i> (Clinton County CCP, No. 752-18)</p>

Plaintiffs' Counsel	Case
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<p>Joseph F. Rice, Esq.* Anne McGinness Kears. Esq. Motley Rice LLC 28 Bridgeside Blvd. Mount Pleasant, SC 29464 jrice@motleyrice.com akearse@motleyrice.com</p>	<p><i>Delaware County, PA v. Purdue Pharma, LP, et al.</i> (Delaware County CCP, No. 2017-008095)</p>
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<p>Donald A. Broggi, Esq. Judy Scolnick, Esq. Beth Kaswan, Esq. Joseph G. Cleemann, Esq. Scott & Scott Attorneys at Law LLP The Helmsley Building 230 Park Avenue, 17th Floor New York, NY 10169 dbroggi@scott-scott.com jscolnick@scott-scott.com bkaswan@scott-scott.com jcleemann@scott-scott.com</p>	<p><i>Delaware County, PA v. Purdue Pharma, LP, et al.</i> (Delaware County CCP, No. 2017-008095)</p> <p><i>Bucks County v. Purdue Pharma, L.P., et al.</i> (Bucks County CCP No. 2018-03144)</p> <p><i>Mercer County v. Purdue Pharma L.P., et al.</i> (Mercer County CCP, No. 2018-01596)</p> <p><i>Clinton County v. Purdue Pharma L.P., et al.</i> (Clinton County CCP, No. 752-18)</p> <p><i>City of Lock Haven v. Purdue Pharma, L.P., et al.</i> (Clinton County CCP, No. 1126-18)</p> <p><i>Warminster Township v. Purdue Pharma, L.P., et al.</i> (Bucks County CCP, No. 2019-01469)</p>

Plaintiffs' Counsel	Case
Richard W. Perhacs, Esq. Erie County Solicitor 140 West 6th Street, Room 504 Erie, PA 16501 rperhacs@eriecountypa.gov	<i>Erie County v. Purdue Pharma L.P., et al.</i> (Erie County CCP, No. 11577-18)
Kim C. Kesner, Esq. Clearfield County Solicitor 212 South Second Street Clearfield, PA 16830 attykesner@atlanticbbs.net	<i>Clearfield County, PA v. Purdue Pharma, L.P.</i> (No. 2018-1484-CD)
Anthony J. D'Amico, Esq. Michael J. D'Amico, Esq. D'Amico Law Offices, LLC 310 Grant Street Grant Building, Suite 825 Pittsburgh, PA 15219 ajd@damicolegal.com mjd@damicolegal.com dlaw@damicolegal.com	<i>Clearfield County, PA v. Purdue Pharma, L.P.</i> (No. 2018-1484-CD)
Theron G. Noble, Esq. Noble Law 301 East Pine Street Clearfield, PA 16830 terry@noblelaw.org	<i>Clearfield County, PA v. Purdue Pharma, L.P.</i> (No. 2018-1484-CD)
Scott M. Hare, Esq. 1806 Frick Building 437 Grant Street Pittsburgh, PA 15219	<i>Adam C. Kassab v. Teva Pharmaceuticals USA, Inc., et al.</i> (Allegheny County CCP No. GD 18-12337)
Arnold Levin, Esq. Daniel C. Levin, Esq. Charles E. Schaffer, Esq. Levin Sedran & Berman LLP 510 Walnut Street, Suite 500 Philadelphia, PA 19106 alevin@lfsblaw.com dlevin@lfsblaw.com cschaffer@lfsblaw.com	<i>Mahoning Township v. Purdue Pharma L.P., et al.</i> (Philadelphia Co. CCP, No. 180603466) <i>Wampum Borough v. Purdue Pharma L.P., et al.</i> (Philadelphia Co. CCP No. 180701963)

Plaintiffs' Counsel	Case
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<p>William S. Consovoy, Esq.* Thomas R. McCarthy, Esq.* Consovoy McCarthy Park PLLC 3033 Wilson Boulevard, Suite 700 Arlington, Virginia 22201 will@consovoymccarthy.com tom@consovoymccarthy.com</p>	<p><i>Adam C. Kassab v. Teva Pharmaceuticals USA, Inc., et al.</i> (Allegheny County CCP No. GD 18-12337)</p>
<p>Joshua M. Neuman, Esq. Kilcoyne & Nesbitt, LLC Union Meeting Corporate Center 925 Harvest Dr., Suite 200 Blue Bell, PA 19422 jneuman@kilcoynelaw.com</p>	<p><i>Adam C. Kassab v. Teva Pharmaceuticals USA, Inc., et al.</i> (Allegheny County CCP No. GD 18-12337)</p>
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Plaintiffs' Counsel	Case
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Individual Defendants' Counsel	Case
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<p>Samuel W. Silver, Esq. John R. Timmer, Esq. Schnader, Harrison, Segal & Lewis LLP 1600 Market Street, Suite 3600 Philadelphia, PA 19103 ssilver@schnader.com jtimmer@schnader.com Counsel for John Kapoor</p>	<p><i>Bucks County v. Purdue Pharma, L.P., et al.</i> (Bucks County CCP No. 2018-03144)</p> <p><i>Delaware County, PA v. Purdue Pharma, LP, et al.</i> (Delaware County CCP, No. 2017-008095)</p>
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<p>Catherine N. Jasons, Esq. Stephen M. Capriotti, Jr. Esq. Kelley Jasons McGowan Spinelli Hanna & Reber, LLP 1818 Market Street, Suite 3205 Philadelphia, PA 19103 cjasons@kjmsh.com scapriotti@kjmsh.com Counsel for Sackler Defendants</p>	<p><i>Delaware County, PA v. Purdue Pharma, LP, et al.</i> (Delaware County CCP, No. 2017-008095)</p> <p><i>Carpenters Health & Welfare of Philadelphia & Vicinity v. Purdue Pharma, L.P., et al.</i> (Philadelphia CCP, No. 180302264)</p>

Individual Defendants' Counsel	Case
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<p>Joshua P. Broudy, Esq. Rosenthal Lurie & Broudy LLC 102 Pickering Way, Suite 310 Exton, PA 19341 josh@rlblawgroup.com Counsel for Stuart D. Baker</p>	<p><i>Carpenters Health & Welfare of Philadelphia & Vicinity v. Purdue Pharma, L.P., et al.</i> (Philadelphia CCP, No. 180302264)</p>
<p>Joseph M. McLaughlin, Esq. Shannon K. McGovern, Esq. Simpson Thacher & Bartlett LLP 425 Lexington Avenue New York, New York 10017 jmclaughlin@stblaw.com smcgovern@stblaw.com Counsel for Stuart D. Baker</p>	<p><i>Carpenters Health & Welfare of Philadelphia & Vicinity v. Purdue Pharma, L.P., et al.</i> (Philadelphia CCP, No. 180302264)</p>

Manufacturer Defendants' Counsel	Case
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<p>Ross B. Galin, Esq. Shara C. Venezia-Walerstein, Esquire O'Melveny & Myers LLP Times Square Tower 7 Times Square New York, NY 10036 rgalin@omm.com svenezia-walerstein@omm.com</p> <p><i>Counsel for Johnson & Johnson; Janssen Pharmaceuticals, Inc.; Ortho-McNeil-Janssen Pharmaceuticals, Inc. (n/k/a/ Janssen Pharmaceuticals, Inc.); and Janssen Pharmaceutica, Inc. (n/k/a/ Janssen Pharmaceuticals, Inc.)</i></p>	<p><i>Delaware County, PA v. Purdue Pharma, LP, et al.</i> (Delaware County CCP, No. 2017-008095)</p>

Manufacturer Defendants' Counsel	Case
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Manufacturer Defendants' Counsel	Case
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Distributor Defendants' Counsel	Case
<p>John N. Joseph, Esq. Abraham J. Rein, Esq. Carolyn H. Kendall, Esq. Post & Schell, P.C. Four Penn Center, 13th Floor 1600 John F. Kennedy Blvd. Philadelphia, PA 19103 jjoseph@postschell.com arein@postschell.com ckendall@postschell.com Counsel for McKesson Corporation</p>	<p><i>Delaware County, PA v. Purdue Pharma, LP, et al.</i> (Delaware County CCP, No. 2017-008095)</p> <p><i>Lackawanna Cty. , PA v. Purdue Pharma, LP, et al.</i> (No. 2017-05156)</p> <p><i>Washington County, PA v. Purdue Pharma, LP, et al.</i> (No. C-63-CV-2017-6268)</p> <p><i>County of York v. Purdue Pharma</i> (No. 2017-SU-003372)</p> <p><i>Township of Bensalem v. Purdue Pharma, L.P., et al.</i> (Bucks County CCP, No. 2018-03199)</p> <p><i>Bradford Cty. v. Purdue Pharma, LP, et al.</i> (No. 2018-CV-0059)</p> <p><i>Huntingdon County v. Purdue Pharma L.P., et al.</i> (Huntingdon County CCP, No. 2018-00784)</p> <p><i>Mercer County v. Purdue Pharma L.P., et al.</i> (Mercer County CCP, No. 2018-01596)</p> <p><i>Clinton County v. Purdue Pharma L.P., et al.</i> (Clinton County CCP, No. 752-18)</p> <p><i>Bucks County v. Purdue Pharma, L.P., et al.</i> (Bucks County CCP No. 2018-03144)</p> <p><i>Monroe Cty. v. Purdue Pharma, L.P., et al.</i> (No. 3972-CV-18)</p> <p><i>Erie County v. Purdue Pharma L.P., et al.</i> (Erie County CCP, No. 11577-18)</p> <p><i>Schuylkill County v. Purdue Pharma L.P., et al.</i> (Schuylkill Co. CCP, No. S-1241-18)</p> <p><i>Tioga County v. Purdue Pharma, L.P., et al.</i> (Tioga Co. CCP, No. 563-CV-2018)</p> <p><i>Clearfield County, PA v. Purdue Pharma, L.P.</i> (No. 2018-1484-CD)</p>

Distributor Defendants' Counsel	Case
<p>Kevin B. Collins, Esq. Steven Winkelman, Esq. Megan A. Crowley, Esq. John Chase Johnson, Esq. John W. Zipp, Esq. Weiss K. Nusraty, Esq. Covington & Burling LLP One City Center 850 Tenth Street, NW Washington, DC 20001 kecollins@cov.com swinkelman@cov.com mcrowley@cov.com jcjohnson@cov.com jzipp@cov.com wnusraty@cov.com Counsel for McKesson Corporation</p>	<p><i>Delaware County, PA v. Purdue Pharma, LP, et al.</i> (Delaware County CCP, No. 2017-008095)</p> <p><i>Bricklayers and Allied Craftworkers Local Union No. 1 of PA/DE Health and Welfare v. Purdue Pharma, L.P., et al.</i> (Philadelphia CCP, No. 180302256)</p>
<p>Marc S. Raspanti, Esq. Douglas K. Rosenblum, Esq. Douglas E. Roberts, Esq. Pietragallo, Gordon, Alfano, Bosick & Raspanti, LLP 1818 Market Street, Suite 3402 Philadelphia, PA 19103 msr@pietragallo.com dkr@pietragallo.com der@pietragallo.com Counsel for Cardinal Health Inc.</p>	<p><i>County of York v. Purdue Pharma</i> (No. 2017-SU-003372)</p> <p><i>Delaware County, PA v. Purdue Pharma, LP, et al.</i> (Delaware County CCP, No. 2017-008095)</p> <p><i>County of Monroe v. Purdue Pharma, L.P., et al.</i> (No. 3972-CV-18)</p> <p><i>Bricklayers and Allied Craftworkers Local Union No. 1 of PA/DE Health and Welfare v. Purdue Pharma, L.P., et al.</i> (Phila. CCP, No. 180302256)</p>
<p>James W. Kraus, Esq. John A. Schwab, Esq. Pietragallo, Gordon, Alfano, Boswick & Raspanti, LLP One Oxford Centre, 38th Floor Pittsburgh, PA 15219 jwk@pietragallo.com jas@pietragallo.com Counsel for Cardinal Health Inc.</p>	<p><i>Lackawanna County, PA v. Purdue Pharma, LP, et al.</i> (No. 2017-05156)</p> <p><i>Washington County, PA v. Purdue Pharma, LP, et al.</i> (No. C-63-CV-2017-6268)</p> <p><i>Cambria County v. Purdue Pharma, LP, et al.</i> (No. 2017-4131)</p> <p><i>Bricklayers and Allied Craftworkers Local Union No. 1 of PA/DE Health and Welfare v. Purdue Pharma, L.P., et al.</i> (Phila. CCP, No. 180302256)</p> <p><i>Clearfield County, PA v. Purdue Pharma, L.P.</i> (No. 2018-1484-CD)</p>

Distributor Defendants' Counsel	Case
<p>Ashley W. Hardin, Esq. F. Lane Heard, III, Esq. Enu A. Mainigi, Esq. Steven M. Pyser, Esq. Miranda Petersen, Esq. Brad Masters, Esq. Williams & Connolly, LLP 725 Twelfth Street, N.W. Washington, D.C. 20005 ahardin@wc.com lheard@wc.com emainigi@wc.com spyser@wc.com mpetersen@wc.com bmasters@wc.com Counsel for Cardinal Health Inc.</p>	<p><i>Delaware County, PA v. Purdue Pharma, LP, et al.</i> (Delaware County CCP, No. 2017-008095)</p> <p><i>Bricklayers and Allied Craftworkers Local Union No. 1 of PA/DE Health and Welfare v. Purdue Pharma, L.P., et al.</i> (Phila. CCP, No. 180302256)</p>
<p>Robert A. Nicholas, Esq. Shannon E. McClure, Esq. Louis Schack, Esq. Neil A. Hlawatsch, Esq. Reed Smith LLP Three Logan Square 1717 Arch Street, Suite 3100 Philadelphia, PA 19103 rnicholas@reedsmith.com smcclure@reedsmith.com lschack@reedsmith.com nhlawatsch@reedsmith.com Counsel for AmerisourceBergen Drug Corporation</p>	<p><i>Delaware County, PA v. Purdue Pharma, LP, et al.</i> (Delaware County CCP, No. 2017-008095)</p> <p><i>County of Lehigh v. Purdue Pharma, LP, et al.</i> (No. 2018-C-0716)</p> <p><i>Bricklayers and Allied Craftworkers Local Union No. 1 of PA/DE Health and Welfare v. Purdue Pharma, L.P., et al.</i> (Philadelphia CCP, No. 180302256)</p>
<p>Jami B. Nimeroff, Esq. Brown McGarry Nimeroff LLC Two Penn Center, Suite 610 1500 JFK Boulevard Philadelphia, PA 19102 jnimeroff@bmnlawyers.com Counsel for Anda, Inc.</p>	<p><i>Delaware County, PA v. Purdue Pharma, LP, et al.</i> (Delaware County CCP, No. 2017-008095)</p>
<p>Ernest F. Koschineg, III, Esq. Jessica M. Heinz, Esq. Cipriani & Werner, P.C. 450 Sentry Parkway, Suite 200 Blue Bell, PA 19422 ekoschineg@c-wlaw.com jheinz@c-wlaw.com Counsel for Breckenridge Pharmaceutical, Inc.</p>	<p><i>Delaware County, PA v. Purdue Pharma, LP, et al.</i> (Delaware County CCP, No. 2017-008095)</p>

Retail Defendants' Counsel	Case
<p>Albert G. Bixler, Esq. Heather R. Olson, Esq. Shari Maynard, Esq. Eckert Seamans Cherin & Mellott, LLC Two Liberty Place 50 South 16th Street, 22nd Floor Philadelphia, PA 19102 abixler@eckertseamans.com holson@eckertseamans.com smaynard@eckertseamans.com</p> <p>Lester C. Houtz, Esq.* Alex J. Harris, Esq.* Andre M. Pauka, Esq. Bartlit Beck Herman Palenchar & Scott, LLP 1801 Wewatta Street, Suite 1200 Denver, CO 80202 Lester.houtz@bartlit-beck.com Alex.harris@bartlit-beck.com andre.pauka@bartlit-beck.com Counsel for Walgreen Eastern Co.</p>	<p><i>Delaware County, PA v. Purdue Pharma, LP, et al.</i> (Delaware County CCP, No. 2017-008095)</p>
<p>James T. Kitchen, Esq. James W. Carlson, Esq. Jones Day 500 Grant Street, Suite 4500 Pittsburgh, PA 15219 jkitchen@jonesday.com jamescarlson@jonesday.com</p> <p>Sarah G. Conway, Esq. Jones Day 555 South Flower Street, 50th Floor Los Angeles, CA 90071 sgconway@jonesday.com</p> <p>Benjamin C. Mizer, Esq. Jones Day 51 Louisiana Avenue, NW Washington, DC 20001 bmizer@jonesday.com</p> <p>Edward M. Carter, Esquire Jones Day 325 John H. McConnell Blvd. Suite 600 Columbus, OH 43215 emcarter@jonesday.com Counsel for Walmart, Inc.</p>	<p><i>Carpenters Health & Welfare of Philadelphia & Vicinity v. Purdue Pharma, L.P., et al.</i> (Philadelphia CCP, No. 180302264)</p> <p><i>Delaware County, PA v. Purdue Pharma, LP, et al.</i> (Delaware County CCP, No. 2017-008095)</p>

Retail Defendants' Counsel	Case
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<p> Thomas E. Hanson, Jr., Esq. Barnes & Thornburg LLP 1000 N. West Street, Suite 1500 Wilmington, DE 19801 thanson@btlaw.com </p> <p> William E. Padgett, Esq. Kathleen L. Matsoukas, Esq. Barnes & Thornburg LLP 11 South Meridian Street Indianapolis, IN 46204 William.padgett@btlaw.com Kathleen.matsoukas@btlaw.com </p> <p> John J. Haggerty, Esq. Fox Rothschild LLP 2700 Kelly Road, Suite 300 Warrington, PA 18976 jhaggerty@foxrothschild.com <i>Counsel for H. D. Smith Wholesale Drug Company</i> </p>	<p><i>Delaware County, PA v. Purdue Pharma, LP, et al. (Delaware County CCP, No. 2017-008095)</i></p>

Retail Defendants' Counsel	Case
<p>Mark D. Villanueva, Esq. Benjamin E. Gordon, Esq. Stradley Ronon Stevens & Young, LLP 2005 Market Street, Suite 2600 Philadelphia, PA 19103 mvillanueva@stradley.com bgordon@stradley.com</p> <p>Conor B. O’Croinin, Esq. Steven N. Herman, Esq. R. Miles Clark, Esq. Zuckerman Spaeder 100 East Pratt Street, Suite 2440 Baltimore, MD 21202 cocroinin@zuckerman.com sherman@zuckerman.com mclark@zuckerman.com Counsel for CVS Pharmacy, Inc.; CVS Indiana, L.L.C.; CVS Rx Services, Inc.; and CVS TN Distribution</p>	<p><i>Carpenters Health & Welfare of Philadelphia & Vicinity v. Purdue Pharma, L.P., et al.</i> (Philadelphia CCP, No. 180302264)</p> <p><i>Delaware County, PA v. Purdue Pharma, LP, et al.</i> (Delaware County CCP, No. 2017-008095)</p>
<p>Ronda L. Harvey, Esq. Jennifer B. Hagedorn, Esq. Unaiza Riaz, Esq. Bowles Rice LLP 600 Quarrier Street Charleston, WV 25301 rharvey@bowlesrice.com jhagedorn@bowlesrice.com uriaz@bowlesrice.com Counsel for Kroger Co.</p>	<p><i>Delaware County, PA v. Purdue Pharma, LP, et al.</i> (Delaware County CCP, No. 2017-008095)</p>

CERTIFICATE OF COMPLIANCE

I certify that this filing complies with the provisions of the *Case Records Public Access Policy of the Unified Judicial System of Pennsylvania* that require filing confidential information and documents differently than non-confidential information and documents.

Dated: February 25, 2020

IMPERATRICE, AMARANT & BELL, P.C.

BY: /s/ Rocco P. Imperatrice, III
ROCCO P. IMPERATRICE, III, ESQUIRE
PA Attorney I.D. 32181
Counsel for Defendants Endo Health Solutions,
Inc. and Endo Pharmaceuticals, Inc.

March 26, 2018 ORDER

IN THE COURT OF COMMON PLEAS OF DELAWARE COUNTY, PENNSYLVANIA

DELAWARE COUNTY, PENNSYLVANIA,

Plaintiff,

v.

PURDUE PHARMA L.P., *et al.*,

Defendants.

:
: No: 2017-008095
:
: Coordinated Civil Actions
:
:
:
:
:
:

NOTICE OF RECENTLY-FILED CASES FOR COORDINATION

Pursuant to this Court's March 26, 2018, June 13, 2018, September 14, 2018, and September 27, 2018 Orders (attached hereto and collectively "the Orders"), the undersigned Defendants hereby give notice that the following action presents common questions of law or fact with those in this coordinated proceeding:

Bedford County, Pennsylvania v. Purdue Pharma L.P., et al. (Bedford County CCP, No. 180-2020)

As set forth in the attached September 27, 2018 Order of this Court, the parties in this case have fourteen days from the date of this notice to object to being part of the coordinated proceeding. If no objection is filed, the case will be deemed part of the coordinated proceeding. Any objection should be filed in accordance with the September 27 Order. Pursuant to the Orders, this case is stayed pending resolution of any objections to being part of the coordinated proceeding.

Dated: February 25, 2020

Respectfully submitted,

IMPERATRICE, AMARANT & BELL, P.C.

By: /s/ Rocco P. Imperatrice, III

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*Counsel for Defendants Endo Health
Solutions Inc. and Endo Pharmaceuticals Inc.*

IN THE COURT OF COMMON PLEAS OF DELAWARE COUNTY, PENNSYLVANIA

DELAWARE COUNTY, PENNSYLVANIA

NO: 17-8095

Plaintiff

JURY TRIAL DEMANDED

v.

PURDUE PHARMA L.P.; PURDUE PHARMA, INC.;
THE PURDUE FREDERICK COMPANY INC.;
TEVA PHARMACEUTICALS USA, INC.;
CEPHALON, INC.; JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.;
ORTHO-McNEIL-JANSSEN PHARMACEUTICALS,
INC. N/K/A JANSSEN PHARMACEUTICALS, INC.;
JANSSEN PHARMACEUTICA, INC. N/K/A
JANSSEN PHARMACEUTICALS, INC.; ENDO
HEALTH SOLUTIONS INC.; ENDO
PHARMACEUTICALS, INC.; PERRY FINE,
SCOTT FISHMAN; and LYNN WEBSTER
Defendants

ORDER

And now, this 26th day of March, 2018, upon consideration of Plaintiff Delaware County's and Defendants' Joint Motion for Pretrial Coordination and Motion for Stay of Actions (the "Motion") and the Responses of the Commonwealth of Pennsylvania, acting by and through Philadelphia District Attorney Lawrence S. Krasner; the City of Philadelphia, the Counties of Northampton, Armstrong, Beaver, Cambria, Fayette, Greene, Lackawanna, Lawrence, Washington, Westmoreland, York and Cumberland; and other interested parties; any supporting memoranda of law and other arguments; and all other replies and responses thereto; and any other argument and prior proceedings in this litigation, it is hereby **ORDERED** and **DECREED** as follows:

1. The criteria for coordination pursuant to Pennsylvania Rule of Civil Procedure 213.1 are satisfied and, therefore, Plaintiff Delaware County's and Defendants' Joint Motion for Pretrial Coordination and Motion for Stay of Actions is **GRANTED**.

2. The following actions are coordinated before the Court of Common Pleas of Delaware County and shall be transferred to this Court pursuant to Pennsylvania Rule of Civil Procedure 213.1 for

all pretrial proceedings, as well as any subsequently filed cases that involve a common question of fact or law:

- a. *Delaware County, Pennsylvania v. Purdue Pharma L.P., et al.* (Delaware Co. CCP, No. 17-8095);
- b. *Commonwealth of Pennsylvania, acting by and through Philadelphia District Attorney Lawrence S. Krasner v. Purdue Pharma L.P., et al.* (Philadelphia CCP, No. 180105594);
- c. *City of Philadelphia v. Allergan PLC, et al.* (Philadelphia CCP, No. 180102718);
- d. *County of Northampton v. Purdue Pharma, L.P., et al.* (Northampton County CCP, No. C48-cv-2017-11557);
- e. *County of Armstrong v. Purdue Pharma L.P., et al.* (Armstrong Co. CCP, No. 2017-1570);
- f. *County of Beaver v. Purdue Pharma, L.P., et al.* (Beaver Co. CCP, No. 11326-2017);
- g. *County of Cambria v. Purdue Pharma, L.P., et al.* (Cambria Co. CCP, No. 2017-4131);
- h. *County of Fayette v. Purdue Pharma, L.P., et al.* (Fayette Co. CCP, No. 2017-2676);
- i. *County of Greene v. Purdue Pharma, L.P., et al.* (Greene Co. CCP, No. 791-2017);
- j. *County of Lackawanna v. Purdue Pharma, L.P., et al.* (Lackawanna Co. CCP, No. 17-cv-5156);
- k. *County of Lawrence v. Purdue Pharma, L.P., et al.* (Lawrence Co. CCP, No. 11180-2017);
- l. *County of Washington v. Purdue Pharma, L.P., et al.* (Washington Co. CCP, No. 2017-6268);
- m. *Westmoreland County v. Purdue Pharma L.P., et al.* (Westmoreland Co. CCP, No. 17C105975);
- n. *County of York v. Purdue Pharma, L.P., et al.* (York Co. CCP, No. 2017-SU-003372);
- o. *County of Cumberland v. Purdue Pharma Inc.* (Cumberland Co. CCP, No. 2018-02147; filed Feb. 13, 2018); and
- p. *Dauphin County, Pennsylvania v. Purdue Pharma L.P., et al.* (Dauphin Co. CCP, No. 2018-cv-716).

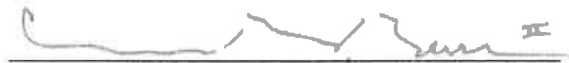
3. Pursuant to Pennsylvania Rule of Civil Procedure 213.1(b), all proceedings in the actions being transferred to Delaware County Court of Common Pleas are stayed until the completion of their transfer to this Court.

4. Pursuant to Pennsylvania Rule of Civil Procedure 213.1(e), the Clerk of this Court shall immediately send a certified copy of this Order to the respective courts in the actions set forth in Paragraphs 2(a)-(p) and a notice to all Plaintiffs and Defendants of this Order immediately upon its entry. Defendants shall also serve this Order on counsel for all parties in the actions set forth in Paragraphs 2(a)-(p).

5. Defendants shall notify this Court of any further similar actions filed against Defendants, and those actions will be transferred to this Court and made part of the proceedings coordinated by this Order.

6. All parties shall bear their own costs in connection with coordination and the litigation of the coordinated actions.

BY THE COURT:

A handwritten signature in dark ink, appearing to read "Charles B. Burr, II", is written over a horizontal line.

Hon. Charles B. Burr, II

J.

June 13, 2018 ORDER

IN THE COURT OF COMMON PLEAS OF DELAWARE COUNTY, PENNSYLVANIA
CIVIL ACTION – LAW

DELAWARE COUNTY, PENNSYLVANIA

No. 17-008095

V.

PURDUE PHARMA, L.P.;
PURDUE PHARMA, INC.;
THE PURDUE FREDERICK COMPANY, INC.;
TEVA PHARMACEUTICALS USA, INC.;
CEPHALON, INC.; JOHNSON & JOHNSON;
JANSSEN PHARMACEUTICALS, INC.;
ORTHO-McNEIL-JANSSEN
PHARMACEUTICALS, INC. N/K/A
JANSSEN PHARMACEUTICALS, INC.;
JANSSEN PHARMACEUTICALS, INC.;
ENDO HEALTH SOLUTIONS, INC.;
ENDO PHARMACEUTICALS, INC.;
PERRY FINE, SCOTT FISHMAN and
LYNN WEBSTER

ORDER

AND NOW, this 13th day of June 2018, upon consideration of the April 9, 2018 and June 8, 2018 Motions of the Manufacturer Defendants (and Plaintiff, Delaware County, and other plaintiffs and defendants who joined or supported those motions), it is ORDERED and DECREED as follows:

1. All parties in the actions attached as Exhibit 1 shall work in good faith to file a Joint Proposed Case Management Order within thirty (30) days of the date of this Order. In the event the parties are unable to reach an agreement on a Joint Proposed Case Management Order, the parties may file separate Proposed Case Management Orders within sixty (60) days of the date of this Order.

2. The proposed Case management Orders shall include a proposed procedure for parties to object to being part of this coordinated proceeding. Until a Case Management Order is entered by the Court providing a procedure to object to a case being part of this coordinated proceeding, the parties shall adhere to the following procedure:

a. Notice of Cases Raising Common Questions. Any party in actions part of this coordinated proceeding shall file with the Court a notice identifying any actions presenting common questions of fact or law. Pursuant to the Court's March 26, 2018 Order, those actions are tentatively "part of the proceeding coordinated". Further, those actions will be stayed pending a determination as set forth in Paragraph 2(b) of this Order.

b. Objection to Transfer. Any party in an action identified in a notice filed with this Court as raising common questions of fact or law can within thirty (30) days of this Order or within fourteen (14) days after the notice is filed (whichever is later), file an objection to being part of the coordinated proceedings with this Court. If no objection is filed within the thirty (30) day period, the Clerk shall send a certified copy of this Order and the notice that the case is part of this proceeding to the court where the action was initially filed to implement the transfer to this Court. If a party files an objection, any party to the coordinated proceeding may file a response to the objection within fourteen (14) days. If the Court rules that the action should not be part of the coordinated proceedings, the action will not be transferred. If the Court finds that the action shall be part of the coordinated proceedings, the Clerk shall send a certified copy of the Order denying the objection to the court where the action was initially filed to implement the transfer to this coordinated proceeding.

3. All actions identified in Exhibit 1 attached to this Order, and any new cases identified in a notice filed with this Court as raising common questions after entry of this Order, are stayed until further order of this Court. Other than steps necessary to comply with this Order, counsel in all actions identified in Exhibit 1 (and cases later noticed as raising common questions) shall not proceed with any activity in those cases in any other court.

BY THE COURT:



CHARLES B. BURR, II S. J.

EXHIBIT 1

1. *Delaware County, Pennsylvania v. Purdue Pharma L.P., et al.*, No. 17-8095 (Delaware Co. Ct. C.P.).
2. *City of Philadelphia v. Allergan PLC, et al.*, No. 002718 (Philadelphia Co. Ct. C.P.).
3. *Commonwealth of Pennsylvania v. Purdue Pharma L.P., et al.*, No. 005594 (Philadelphia Co. Ct. C.P.).
4. *County of Armstrong v. Purdue Pharma, L.P., et al.*, No. 2017-1570-GV (Armstrong Co. Ct. C.P.).
5. *County of Beaver v. Purdue Pharma, L.P., et al.*, No. 11326-2017 (Beaver Co. Ct. C.P.).
6. *County of Cambria v. Purdue Pharma, L.P., et al.*, No. 2017-4131 (Cambria Co. Ct. C.P.).
7. *County of Cumberland v. Purdue Pharma L.P., et al.*, No. 2018-02147 (Cumberland Co. Ct. C.P.).
8. *Dauphin County v. Purdue Pharma L.P., et al.*, No. 2018-CV-716-CV (Dauphin Co. Ct. C.P.).
9. *County of Fayette v. Purdue Pharma, L.P., et al.*, No. 2017-2676 (Fayette Co. Ct. C.P.).
10. *County of Greene v. Purdue Pharma, L.P., et al.*, No. 791-2017 (Greene Co. Ct. C.P.).
11. *County of Lackawanna v. Purdue Pharma, L.P., et al.*, No. 17-CV-5156 (Lackawanna Co. Ct. C.P.).
12. *County of Lawrence v. Purdue Pharma, L.P., et al.*, No. 11180-17 (Lawrence Co. Ct. C.P.).
13. *County of Northampton v. Purdue Pharma, L.P., et al.*, No. C48-cv-2017-11557 (Northampton Co. Ct. C.P.).
14. *County of Washington v. Purdue Pharma, L.P., et al.*, No. 2017-6268 (Washington Co. Ct. C.P.).
15. *Westmoreland County v. Purdue Pharma, L.P., et al.*, No. 2017-5975 (Westmoreland Co. Ct. C.P.).
16. *County of York v. Purdue Pharma, L.P., et al.*, No. 2017-SU-003372 (York Co. Ct. C.P.).
17. *AFSCME District Council 33 Health & Welfare Fund v. Purdue Pharma, L.P., et al.*, No. 180302569 (Philadelphia Co. Ct. C.P.).

18. *AFSCME District Council 47 Health & Welfare Fund v. Purdue Pharma, L.P., et al.*, No. 180302255 (Philadelphia Co. Ct. C.P.).
19. *County of Bradford v. Purdue Pharma, L.P., et al.*, No. 2018CV0059 (Bradford Co. Ct. C.P.).
20. *Bricklayers and Allied Craftworkers Union No. 1 of PA/DE Health and Welfare Fund v. Purdue Pharma, L.P., et al.*, No. 180302256 (Philadelphia Co. Ct. C.P.).
21. *County of Carbon v. Purdue Pharma, L.P., et al.*, No. 18-0990 (Carbon Co. Ct. C.P.).
22. *Carpenters Health & Welfare of Philadelphia & Vicinity v. Purdue Pharma, L.P., et al.*, No. 180302264 (Philadelphia Co. Ct. C.P.).
23. *County of Clarion v. Purdue Pharma, L.P., et al.*, No. 285 CD 2018 (Clarion Co. Ct. C.P.).
24. *The Trustees of the Unite Here Local 634 Health & Welfare Fund v. Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, et al.*, No. 180401123 (Philadelphia Co. Ct. C.P.).
25. *The Commonwealth of Pennsylvania by James B. Martin, District Attorney of Lehigh County, et al. v. Purdue Pharma, L.P., et al.*, No. 2018-C-0716 (Lehigh Co. Ct. C.P.).
26. *SEPTA v. Endo Pharmaceuticals, Inc., et al.*, No. 180302923 (Philadelphia Co. Ct. C.P.).
27. *Philadelphia Federation of Teachers Health and Welfare Fund v. Endo Pharmaceuticals Inc., et al.*, No. 003891 (Philadelphia Co. Ct. C.P.).
28. *UFCW, Local 23 and Employers Health Fund v. Endo Pharmaceuticals Inc., et al.*, No. 003485 (Philadelphia Co. Ct. C.P.).
29. *City of Pittsburgh v. Purdue Pharma L.P., et al.*, No. 18-006153 (Allegheny Co. Ct. C.P.).
30. *County of Allegheny v. Purdue Pharma L.P., et al.*, No. 18-006155 (Allegheny Co. Ct. C.P.).
31. *Bucks County v. Purdue L.P. et al.*, No. 2018-03144 (Bucks Co. Ct. C.P.).
32. *Township of Bensalem v. Purdue Pharma L.P., et al.*, No. 2018-03199 (Bucks Co. Ct. C.P.).
33. *Iron Workers District Council of Philadelphia and Vicinity Benefit Fund v. Abbott Labs. et al.*, No. 00244 (Philadelphia County Ct. C.P.).

September 14, 2018 ORDER

IN THE COURT OF COMMON PLEAS OF DELAWARE COUNTY,
PENNSYLVANIA
CIVIL ACTION – LAW

DELAWARE COUNTY,
PENNSYLVANIA

v.

PURDUE PHARMA, L.P., *et al*

NO. 2017-008095

COORDINATED CIVIL ACTIONS

CASE MANAGEMENT ORDER NO. 1

AND NOW, this ~~14~~th day of September, 2018, intending to conform with Pa.R.C.P. 213.1, and consistent with Pa.R.A.P. 1701(b), this Court having determined certain procedure is needed to coordinate these civil actions which, among other claims, allege mismanagement, mishandling and/or misuse of certain synthetic compounds produced lawfully for medical use, known generally as opioids ("Pennsylvania Opioid Litigation"), it is hereby ORDERED and DECREED, as follows:

1. THE COORDINATED CASES.

The cases subject to the March 26, 2018 Order of this Court ("Coordination Order") are identified as the Coordinated Cases and listed at Exhibit "A" attached hereto. The Coordinated Cases shall include any

subsequently filed civil case which includes a common question of fact or law and is transferred to this Court.

2. PURPOSE AND SCOPE OF ORDER.

(a) This Case Management Order ("CMO") is intended to conserve judicial resources, avoid duplicative motion practice and discovery to the fullest extent practicable, serve the convenience of the parties and witnesses, pursuant to Pa.R.C.P. 126, promote the just, speedy and inexpensive conduct of the litigation, and mediate the compromise and settlement of the parties' claims and defenses. This CMO and, unless otherwise specified, any subsequent pretrial case management order issued in the Coordinated Cases, shall govern pretrial proceedings in all of the Coordinated Cases, including any that may subsequently be transferred to this Court under Pa.R.C.P. 213.1.

(b) This CMO may be amended by the Court at any time. Any party may apply to the Court to modify or amend this CMO in any respect. The Court may issue subsequent case management orders further addressing pretrial proceedings in the Coordinated Cases.

3. APPLICATION TO ALL PARTIES.

This Order and all subsequent case management and pretrial orders shall be binding upon all parties and counsel in each civil action subject to this coordinated proceeding, unless the order expressly states it relates only to a specific action or party.

4. COMMUNICATION WITH THE COURT.

All substantive communication with the Court shall be filed of record without exception.

5. PRESERVATION.

All parties and counsel in each civil action subject to this coordinated proceeding are reminded of their obligation, consistent with the law of the Commonwealth of Pennsylvania and specifically the Pennsylvania Supreme Court Rules of Civil Procedure, to take reasonable measures to preserve for production, inspection, copying, testing, or sampling, those documents (including writings, drawings, graphs, charts, photographs, and electronically stored information), tangible things or electronically stored information, which constitute or contain materials within the scope of Pa.R.C.P. 4003.1 through 4003.6 and are in the possession, custody or control of a party, or are known by a party to be in the possession custody or control of a non-party.

6. COUNTERPART FEDERAL LITIGATION.

This Court acknowledges there are a number of federal civil actions which are similar on their facts to the Coordinated Cases now assigned as part of *In re: National Prescription Opiate Litigation*, MDL No. 2804 ("MDL 2804")(www.ohnd.uscourts.gov/mdl-2804). To achieve the efficiency, benefit and purpose of the Coordination Order, this Court intends to conform with the discovery, settlement and litigation procedures and protocols implemented for specific use in MDL 2804 in its case management of the Coordinated Cases.

7. CAPTIONS, DOCKETING, FILING AND SERVICE.

(a) CAPTIONS.

The caption used on each document to be docketed by a party will be the individual caption and number assigned by the Office of Judicial Support of Delaware County. The caption to be docketed by this Court will be *Delaware County, Pennsylvania v. Purdue Pharma, L.P., et al*, No. 2017-008095, ("Coordinated Civil Actions Docket").

(b) DOCKETING.

Each order, decision and opinion entered by this Court on the Coordinated Civil Action Docket will also be entered on the individual docket for each of the Coordinated Cases.

(c) FILING AND SERVICE.

(1). Electronic Service. Each document any party files with or submits to this Court shall be served electronically by email upon each party in each of the Coordinated Cases by forwarding the document to each counsel of record. Service by electronic file transfer to the Schedule of Electronic Distribution described at paragraph 7.(c)(2) below shall constitute service under this paragraph. Each counsel of record must establish an electronic filing account with the Office of Judicial Support of Delaware County, immediately.

(2). Electronic Service Lists. Co-Lead Counsel for Plaintiffs, Manufacturer Defendants, Distributor Defendants, and Physician Defendants each respectively shall establish the Schedule of Email Distribution to which any party may send court filings or other case documents for service upon each party in the Coordinated Cases. The Schedule of Email Distribution shall be entered upon the Coordinated Civil Actions Docket within thirty (30) days of this CMO, and as necessary from time to time shall be amended of record on that same docket.

8. STAY OF CASES AGAINST PHYSICIAN DEFENDANTS.

The Coordinated Cases shall be stayed as to the Physician Defendants for a period of ninety (90) days from the entry of this Order. As to the Physician Defendants only, all deadlines established by this CMO shall commence from the expiration of the stay, barring application by the Physician Defendants to extend the stay.

9. PRELIMINARY OBJECTIONS.

(a) Preliminary Objection Test Cases. The intention of this Court is to coordinate briefing on preliminary objections ("POs") that may be filed under Pa.R.C.P. 1028, avoid duplication, and ensure efficiency given that there is substantial overlap of parties, fact patterns and legal claims and defenses within the Coordinated Cases. At the same time, this Court intends to preserve the parties' ability to separately brief POs as to any claims and defenses that may be unique to any specific party or individual case among the Coordinated Cases. Accordingly, this Court will hear POs in the Coordinated Cases in the following selected test cases (collectively, the "PO Test Cases"):

(1). *Delaware County, Pennsylvania v. Purdue Pharma, L.P., et al.* (Delaware Co. CCP No. 2017-008095).

(2). *County of Carbon v. Purdue Pharma, L.P., et al.* (Carbon Co. CCP No. 2018-0990).

(3). *Commonwealth of Pennsylvania, acting by and through Philadelphia District Attorney Lawrence S. Krasner v. Purdue Pharma, L.P., et al.* (Phila. Co. CCP No. 18010559).

(4). *Carpenters Health & Welfare of Philadelphia & Vicinty v. Purdue Pharma, L.P., et al.* (Phila. Co. CCP No. 180302264).

These selected test cases include a test case for civil actions brought by: (1) county/municipal plaintiffs against manufacturer defendants and physician defendants; (2) county/municipal plaintiffs against distributor defendants; (3) plaintiffs purporting to represent the Commonwealth; and (4) third-party payor plaintiffs.

(b) Amendments to PO Test Case Complaints. On or by Wednesday, November 14, 2018, Plaintiffs must file any amendments to the PO Test Case complaints or otherwise provide notice in writing to Defendants that the PO Test Case complaints will not be amended prior to the filing of POs.

(c) Non-PO Test Cases. Except upon motion, hearing and further order of this Court, Defendants do not need to file preliminary objections or otherwise respond to the complaints in any of the other actions in the Coordinated Cases. This Court recognizes not all Defendants in the Coordinated Cases are parties to the PO Test Cases. Those Defendants who are not parties to the PO Test Cases do not forfeit or waive any rights

by reason of the entry of this CMO and their non-participation in the PO Test Cases, and will be afforded the opportunity to assert their defenses in Non-PO Test Cases at the appropriate time once this Court has decided the preliminary objections raised pursuant to this CMO in the PO Test Cases.

(d) POs – Form, Deadlines, and Page Limits.

(1). On or by Friday, December 14, 2018, the Manufacturer Defendants, Distributor Defendants, and Physician Defendants in the PO Test Cases shall each file combined POs and memoranda in support to the PO Test Case complaints addressing arguments common to each group of Defendants, respectively (i.e., Manufacturer Defendants shall file a single brief, Distributor Defendants shall file a single brief, and Physician Defendants shall file a single brief). Each brief (not including preliminary objections or attachments) shall not exceed 75 pages.

(2). On or by Friday, December 14, 2018, each Defendant named in the PO Test Cases may choose to file separate POs addressing issues specific to it. Defendant-specific POs may incorporate by reference arguments and objections addressed in the combined briefs. Defendant-specific briefs shall not exceed 20 pages (not including preliminary objections or attachments).

(3). On or by 60 days from the expiration of the stay imposed by Paragraph 8, Physician Defendants shall file their POs to the PO Test Case complaints. The Physician Defendants are permitted to address any and all issues raised in any previously-filed Preliminary Objections or Motion for Reconsideration in their Test Case POs.

(4). On or by Friday, January 4, 2019, Defendants in the *Commonwealth of Pennsylvania and Carpenters Health & Welfare of Philadelphia & Vicinity* POs Test Case shall file POs. Each brief shall conform to the length and other standards described herein at paragraph 9(d)(1).

(e) Opposition and Replies – Form, Deadlines, and Page Limits.

Plaintiffs may respond to the POs within 45 days after the POs are filed. Defendants may file replies to PO responses within 30 days thereafter. Plaintiffs shall file one opposition brief for each combined PO brief and one for each Defendant specific brief. Co-Lead Counsel for Plaintiffs shall coordinate with Plaintiffs in Non-PO Test Cases to ensure those Plaintiffs' arguments are included in all opposition briefs. Briefs responding to Defendants' combined briefs shall be limited to 75 pages (not including attachments). Briefs responding to Defendant-specific briefs shall be limited to 20 pages (not including attachments). Replies in support of

combined POs shall be limited to 25 pages (not including attachments). Replies in support of Defendant-specific POs shall be limited to 15 pages (not including attachments).

(f) No Waiver or Forfeiture.

(1). Nothing in this paragraph 9 of the CMO shall be deemed a waiver or forfeiture of any right of any Plaintiff.

(2). Nothing in this paragraph 9 of the CMO shall be deemed a waiver or forfeiture of any right of any Defendant.

10. DISCOVERY PROCEDURE.

This Court finding, within the meaning of Pa.R.C.P. 126, the substantial rights of the parties to the Coordinated Cases will not be affected, directs the parties to conduct discovery in the Coordinated Cases in substantial conformity with Pa.R.C.P. 4001 through 4020, except as provided in this CMO:

(a) Discovery Period. All pretrial discovery shall commence in the Coordinated Cases immediately upon entry of this CMO. All pretrial discovery shall be completed by Friday, November 1, 2019.

(b) Supervision of Discovery. A significant reason for the Coordinated Order is to avoid duplicative motion practice and discovery in

the Coordinated Cases by assigning responsibility to this Court. This Court will preside over pretrial discovery in each of the Coordinated Cases.

(c) MDL 2804 Pretrial Discovery. To the extent any defendant in the Coordinated Cases has produced or will produce discovery through any method substantially similar to those identified at Pa.R.C.P. 4001(c) and (d), or through any protocol or procedure implemented by the Court in MDL 2804, those defendants shall, as soon as practicable and at no cost to the plaintiffs in the Coordinated Cases, deliver duplicate copies of those productions ("MDL 2804 Discovery Productions") to Co-Lead Counsel for the Plaintiffs in the Coordinated Cases. This obligation to deliver MDL 2804 Discovery Production is continuing meaning: defendants shall deliver to Co-Lead Counsel in the Coordinated Cases any additional discovery the defendant produces to plaintiffs in MDL 2804 after entry of this CMO. Co-Lead Counsel for Defendants and Plaintiffs will mutually agree upon the time, place and method to complete delivery of the MDL 2804 Discovery Productions.

(d) MDL 2804 Written, Documentary and Deposition Protocols. The pretrial discovery protocols implemented in MDL 2804 are approved and implemented by this CMO for the use of all parties in the Coordinated Cases in pretrial discovery.

(e) Discovery Procedure, Generally. Other than as hereinabove specifically directed, discovery shall be conducted in substantial compliance with the Pennsylvania Supreme Court Rules of Civil Procedure, the Local Rules of Civil Procedure adopted in Delaware County, including Del.Co. Local Rule 205.4 *Electronic Filing and Service of Legal Papers in Delaware County*, and the *Delaware County Public Access Policy Local Rule* adopted as a Local Rule of Judicial Administration on June 26, 2018, at *In re: Case Records Public Access Policy of the Unified Judicial System of Pennsylvania*, Delaware County Common Pleas Court Civil Docket No. 2017-005120.

(f) Expert Witnesses and Opinion Testimony. Within forty-five (45) days of the entry of this CMO, Co-Lead Counsel shall confer and by stipulation agree upon protocols for the discovery of expert testimony. The protocols agreed upon by stipulation may be in lieu of the civil procedure described at Pa.R.C.P. 4003.5.

11. MISCELLANEOUS.

(a) Local Rules. The provisions of this CMO, and any subsequent case management or pretrial orders issued in the Coordinated Cases, shall supersede any inconsistent provisions of the Local Rules for the Court of Common Pleas of Delaware County.

(b) Time Computation. Days, as referenced in this CMO, shall be completed pursuant to Pa.R.C.P. 106.

(c) Extension of Deadlines. Nothing in this CMO shall be interpreted to restrict the ability of the parties to move, separately or (preferably) jointly, for an extension of any deadline set by this order.

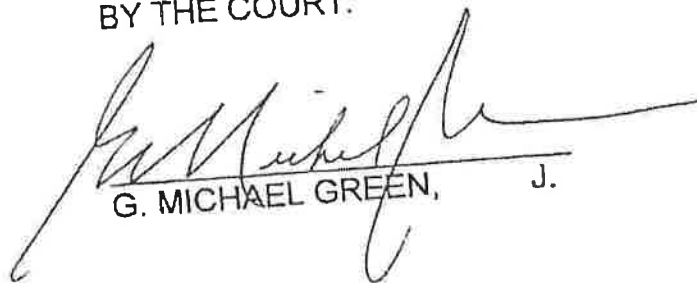
(d) Protective Order. Documents, testimony, and other discovery in this Coordinated Cases may involve production of confidential, proprietary, and private information for which special protection from public disclosure and from using discovery for any purpose other than this litigation would be warranted. The parties in the Coordinated Cases shall meet and confer and, within 45 days of the entry of this Order, file with the Court a proposed protective order governing the protection of confidential, proprietary, and private information. The parties shall state in this proposed protective order the areas on which they agree, and their respective positions where they may disagree.

(e) Document Production Protocol. The Court encourages the parties in the Coordinated Cases to adopt a Document Production Protocol governing the format of production of documents.

(f) Continuance Requests. Once dates are scheduled, the Court is reluctant to grant continuances. If a continuance is requested, the parties shall file an appropriate Motion for Continuance.

(g) Documents. Courtesy copies of each document filed with the Office of Judicial Support shall be furnished to this Court contemporaneously with the filing.

BY THE COURT:



G. MICHAEL GREEN, J.

COORDINATED CASES

1. *Delaware County, Pennsylvania v. Purdue Pharma, L.P., et al.*, No. 17-8095 (Delaware Co. Ct. C.P.).
2. *City of Pittsburgh v. Purdue Pharma, L.P., et al.*, No. 18-006153 (Allegheny Co. Ct. C.P.).
3. *County of Allegheny v. Purdue Pharma, L.P., et al.*, No. 18-006155 (Allegheny Co. Ct. C.P.).
4. *City of Philadelphia v. Allerga PLC, et al.*, No. 18002718 (Philadelphia Co. Ct. C.P.)
5. *Commonwealth of Pennsylvania v. Purdue Pharma L.P., et al.*, No. 18005594 (Philadelphia Co. Ct. C.P.).
6. *County of Armstrong v. Purdue Pharma, L.P., et al.*, No. 2017-1570-GV (Armstrong Co. Ct. C.P.).
7. *County of Beaver v. Purdue Pharma, L.P., et al.*, No. 11326-2017 (Beaver Co. Ct. C.P.).
8. *County of Cambria v. Purdue Pharma L.P., et al.*, No. 2017-4131 (Cambria Co. Ct. C.P.).
9. *County of Cumberland v. Purdue Pharma L.P., et al.*, No. 2018-02147 (Cumberland Co. Ct. C.P.).
10. *Dauphin County v. Purdue Pharma L.P., et al.*, No. 2018-CV-716-CV (Dauphin Co. Ct. C.P.).
11. *County of Fayette v. Purdue Pharma L.P., et al.*, No. 2017-2676 (Fayette Co. Ct. C.P.).
12. *County of Greene v. Purdue Pharma L.P., et al.*, No. 791-2017 (Greene Co. Ct. C.P.).

13. *County of Lackawanna v. Purdue Pharma L.P., et al.*, No. 17-CV-5156 (Lackawanna Co. Ct. C.P.).
14. *County of Lawrence v. Purdue Pharma L.P., et al.*, No. 11180-17 (Lawrence Co. Ct. C.P.).
15. *County of Northampton v. Purdue Pharma L.P., et al.*, No. C84-cv 2017-11557 (Northampton Co. Ct. C.P.).
16. *County of Washington v. Purdue Pharma L.P. et al.*, No.2017-6268 (Washington Co. Ct. C.P.).
17. *Westmoreland County v. Purdue Pharma L.P., et al.*, No. 2017-5975 (Westmoreland Co. Ct. C.P.).
18. *County of York v. Purdue Pharma L.P., et al.*, No. 2017-SU-003372 (York Co. Ct. C.P.).
19. *AFSCME District Council 33 Health & Welfare Fund v. Purdue Pharma L.P., et al.*, No. 180302569 (Philadelphia Co. Ct. C.P.).
20. *AFSCME District Council 47 Health & Welfare Fund v. Purdue Pharma L.P., et al.*, No. 180302255 (Philadelphia Co. Ct. C.P.).
21. *County of Bradford v. Purdue Pharma L.P., et al.*, No. 2018CV0059 (Bradford Co. Ct. C.P.).
22. *Bricklayers and Allied Craftworkers Union No. 1 of PA/DE Health and Welfare Fund v. Purdue Pharma L.P., et al.*, No. 180302256 (Philadelphia Co. Ct. C.P.).
23. *County of Carbon v. Purdue Pharma L.P., et al.*, No.18-0990 (Carbon Co. Ct. C.P.).
24. *Carpenters Health & Welfare of Philadelphia & Vicinity v. Purdue Pharma L.P., et al.*, No. 180302264 (Philadelphia Co. Ct. C.P.).
25. *County of Clarion v. Purdue Pharma L.P., et al.*, No. 285 CD 2018 (Clarion Co. Ct. C.P.).

26. *The Trustees of the Unite Here Local 634 Health & Welfare Fund v. Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, et al.*, No. 180401123 (Philadelphia Co. Ct. C.P.).
27. *The Commonwealth of Pennsylvania by James B. Martin, District Attorney of Lehigh County, et al v. Purdue Pharma L.P., et al.*, No.2018-C-0716 (Lehigh Co. Ct. C.P.).
28. *SEPTA v. Endo Pharmaceuticals, Inc., et al.*, No. 180302923 (Philadelphia Co. Ct. C.P.).
29. *Philadelphia Freedom of Teachers Health and Welfare Fund v. Endo Pharmaceuticals, Inc., et al.*, No. 003891 (Philadelphia Co. Ct. C.P.).
30. *UFCW, Local 23 and Employers Health Fund v. Endo Pharmaceuticals, Inc., et al.*, No. 003485 (Philadelphia Co. Ct. C.P.).
31. *County of Erie v. Purdue Pharma L.P., et al.*, (Erie Co. CCP No.11577-18).
32. *Clinton County v. Purdue Pharma L.P., et al.* (Clinton Co. CCP, No. 752-18).
33. *County of Huntingdon v. Purdue Pharma L.P., et al.* (Huntingdon Co. CCP, No. 2018-0784).
34. *Mahoning Township v. Purdue Pharma L.P., et al.* (Philadelphia Co. CCP No. 180603466).
35. *County of Mercer v. Purdue Pharma L.P., et al.* (Mercer Co. CCP No. 2018-1596).
36. *County of Monroe v. Purdue Pharma L.P., et al.* (Monroe Co. CCP No. 3972CU18).
37. *Pike County v. Purdue Pharma L.P., et al.* (Pike Co. CCP No. 602-2018).
38. *Township of Bensalem v. Purdue Pharma L.P., et al.* (Bucks CCP No. 2018-03119).

39. *Schuylkill County v. Purdue Pharma L.P., et al.* (Schuylkill CCP No. S-1241-18).

40. *Tioga County v. Purdue Pharma L.P., et al.* (Tioga CCP No. 563 CV 2018).

41. *Iron Workers District Council of Philadelphia and Vicinity Benefit Fund v. Abbott Labs, et al.*, No. 18052442 (Philadelphia Co. Ct. C.P.)

September 27, 2018 ORDER

IN THE COURT OF COMMON PLEAS OF DELAWARE COUNTY,
PENNSYLVANIA
CIVIL ACTION – LAW

DELAWARE COUNTY,
PENNSYLVANIA

v.

PURDUE PHARMA, L.P., *et al*

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NO. 2017-008095

COORDINATED CIVIL ACTIONS

ORDER

AND NOW, this 27th day of September, 2018, upon notification provided consistent with this Court's March 26, 2018 Order of similar actions that involve a common question of fact or law and in conformity with the September 21, 2018 Memorandum and Order of the Honorable P. Kevin Brobson, it is hereby ORDERED and DECREED as follows:

1. The following actions are coordinated before the Court of Common Pleas of Delaware County and shall be transferred to this Court pursuant to Pennsylvania Rule of Civil Procedure 213.1 for all pretrial proceedings, as well as any subsequently filed cases that involve a common question of fact or law:

(a) *City of Pittsburgh v. Purdue Pharma, L.P., et al.*, No. 18-006153
(Allegheny Co. Ct. C.P.).

(b) *County of Allegheny v. Purdue Pharma, L.P., et al.*, No. 18-006155
(Allegheny Co. Ct. C.P.).

- (c) *AFSCME District Council 33 Health & Welfare Fund v. Purdue Pharma L.P., et al.*, No. 180302569 (Philadelphia Co. Ct. C.P.).
- (d) *AFSCME District Council 47 Health & Welfare Fund v. Purdue Pharma L.P., et al.*, No. 180302255 (Philadelphia Co. Ct. C.P.).
- (e) *County of Bradford v. Purdue Pharma L.P., et al.*, No. 2018CV0059 (Bradford Co. Ct. C.P.).
- (f) *Bricklayers and Allied Craftworkers Union No. 1 of PA/DE Health and Welfare Fund v. Purdue Pharma L.P., et al.*, No. 180302256 (Philadelphia Co. Ct. C.P.).
- (g) *County of Carbon v. Purdue Pharma L.P., et al.*, No. 18-0990 (Carbon Co. Ct. C.P.).
- (h) *Carpenters Health & Welfare of Philadelphia & Vicinity v. Purdue Pharma L.P., et al.*, No. 180302264 (Philadelphia Co. Ct. C.P.).
- (i) *County of Clarion v. Purdue Pharma L.P., et al.*, No. 285 CD 2018 (Clarion Co. Ct. C.P.).
- (j) *The Trustees of the Unite Here Local 634 Health & Welfare Fund v. Janssen Pharmaceutica, Inc. n/k/a Janssen Pharmaceuticals, et al.*, No. 180401123 (Philadelphia Co. Ct. C.P.).
- (k) *The Commonwealth of Pennsylvania by James B. Martin, District Attorney of Lehigh County, et al v. Purdue Pharma L.P., et al.*, No. 2018-C-0716 (Lehigh Co. Ct. C.P.).
- (l) *SEPTA v. Endo Pharmaceuticals, Inc., et al.*, No. 180302923 (Philadelphia Co. Ct. C.P.).
- (m) *Philadelphia Freedom of Teachers Health and Welfare Fund v. Endo Pharmaceuticals, Inc., et al.*, No. 003891 (Philadelphia Co. Ct. C.P.).
- (n) *UFCW, Local 23 and Employers Health Fund v. Endo Pharmaceuticals, Inc., et al.*, No. 003485 (Philadelphia Co. Ct. C.P.).

- (o) *County of Erie v. Purdue Pharma L.P., et al.*, (Erie Co. CCP No. 11577-18).
- (p) *Clinton County v. Purdue Pharma L.P., et al.* (Clinton Co. CCP, No. 752-18).
- (q) *County of Huntingdon v. Purdue Pharma L.P., et al.* (Huntingdon Co. CCP, No. 2018-0784).
- (r) *Mahoning Township v. Purdue Pharma L.P., et al.* (Philadelphia Co. CCP No. 180603466).
- (s) *County of Mercer v. Purdue Pharma L.P., et al.* (Mercer Co. CCP No. 2018-1596).
- (t) *County of Monroe v. Purdue Pharma L.P., et al.* (Monroe Co. CCP No. 3972CU18).
- (u) *Pike County v. Purdue Pharma L.P., et al.* (Pike Co. CCP No. 602-2018).
- (v) *Township of Bensalem v. Purdue Pharma L.P., et al.* (Bucks CCP No. 2018-03119).
- (w) *Schuylkill County v. Purdue Pharma L.P., et al.* (Schuylkill CCP No. S-1241-18).
- (x) *Tioga County v. Purdue Pharma L.P., et al.* (Tioga CCP No. 563 CV 2018).
- (y) *Iron Workers District Council of Philadelphia and Vicinity Benefit Fund v. Abbott Labs, et al.*, No. 18052442 (Philadelphia Co. Ct. C.P.).
- (z) *Bucks County v. Purdue Pharma L.P., et al.* (Bucks CCP No. 2018-03144).
- (aa) *Wampum Borough v. Purdue Pharma L.P., et al.* (Lawrence County, CCP No. 180701963).

2. Pursuant to Pennsylvania Rule of Civil Procedure 213.1(b), all proceedings in the actions being transferred to Delaware County Court of Common Pleas for coordination are stayed until the completion of their transfer to this Court.

3. **Objection to Coordination Procedure.** Any party in an action identified in a notice filed with this Court raising common questions of law or fact may within thirty (30) days of this Order or within fourteen (14) days after the notice is filed (whichever is later), file an objection to participation in this Coordination of Civil Actions with the Office of Judicial Support of Delaware County, Delaware County Courthouse, 201 W. Front Street, Media, Pennsylvania 19063. Where no objection is filed, the Office of Judicial Support shall send a certified copy of this Order and the notice that the action is part of this proceeding to the Court of Common Pleas in which the action was initially filed to implement coordination. When a party files an objection, any party to the coordinated proceeding may file a response to the objection within fourteen (14) days. Following an objection, if this Court determines the action should not be part of the coordinated proceedings, the action will not be transferred; however, if this Court determines the action should be part of the coordinated proceedings, the Office of Judicial Support of Delaware County shall send a certified copy of

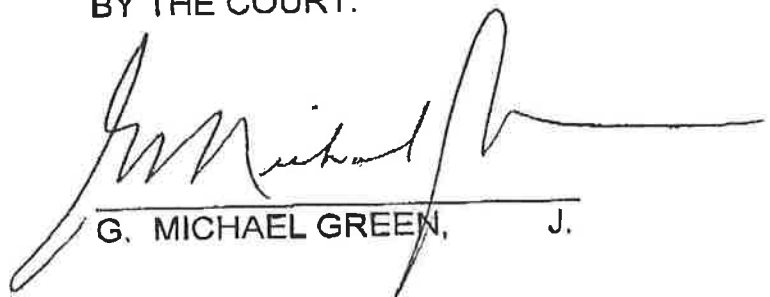
the Order denying the objection to the Court of Common Pleas in which the action was initially filed to implement transfer of the action to this coordinated proceeding.

4. Pursuant to Pennsylvania Rule of Civil Procedure 213.1(e), the Office of Judicial Support shall immediately send a certified copy of this Order to the respective courts in the actions set forth in Paragraph 1(a)-(aa) and a notice to all Plaintiffs and Defendants of this Order immediately upon its entry. Defendants shall also serve this Order on counsel for all parties in the actions set forth in Paragraphs 1(a)-(aa).

5. Defendants shall notify this Court of any further similar actions filed against Defendants, and those actions shall be transferred to this Court and made part of the proceedings coordinated by this Order.

6. All parties shall bear their own costs in connection with coordination and the litigation of the coordinated actions.

BY THE COURT:



G. MICHAEL GREEN, J.

***Bedford County, Pa. v. Purdue
Pharma L.P., et al. (Bedford
County CCP, No.
180-2020) - COMPLAINT***

Supreme Court of Pennsylvania

Court of Common Pleas

Civil Cover Sheet

Bedford

County

For Prothonotary Use Only:

Docket No:

180-2020

The information collected on this form is used solely for court administration purposes. This form does not supplement or replace the filing and service of pleadings or other papers as required by law or rules of court.

Commencement of Action:

- ☒ Complaint ☐ Writ of Summons ☐ Petition
☐ Transfer from Another Jurisdiction ☐ Declaration of Taking

Lead Plaintiff's Name:

Bedford County

Lead Defendant's Name:

Purdue Pharma L.P.

Are money damages requested? ☒ Yes ☐ No

Dollar Amount Requested: ☐ within arbitration limits
☒ outside arbitration limits
(check one)

Is this a Class Action Suit? ☐ Yes ☒ No

Is this an MDJ Appeal? ☐ Yes ☒ No

Name of Plaintiff/Appellant's Attorney: Joseph J. Cappelli; Barry J. Scatton

☐ Check here if you have no attorney (are a Self-Represented [Pro Se] Litigant)

Nature of the Case: Place an "X" to the left of the ONE case category that most accurately describes your **PRIMARY CASE**. If you are making more than one type of claim, check the one that you consider most important.

TORT (do not include Mass Tort)

- ☐ Intentional
☐ Malicious Prosecution
☐ Motor Vehicle
☐ Nuisance
☐ Premises Liability
☒ Product Liability (does not include mass tort)
☐ Slander/Libel/ Defamation
☐ Other:

CONTRACT (do not include Judgments)

- ☐ Buyer Plaintiff
☐ Debt Collection: Credit Card
☐ Debt Collection: Other
☐ Employment Dispute: Discrimination
☐ Employment Dispute: Other
☐ Other:

CIVIL APPEALS

- Administrative Agencies
☐ Board of Assessment
☐ Board of Elections
☐ Dept. of Transportation
☐ Statutory Appeal: Other

- ☐ Zoning Board
☐ Other:

MASS TORT

- ☐ Asbestos
☐ Tobacco
☐ Toxic Tort - DES
☐ Toxic Tort - Implant
☐ Toxic Waste
☐ Other:

REAL PROPERTY

- ☐ Ejectment
☐ Eminent Domain/Condemnation
☐ Ground Rent
☐ Landlord/Tenant Dispute
☐ Mortgage Foreclosure: Residential
☐ Mortgage Foreclosure: Commercial
☐ Partition
☐ Quiet Title
☐ Other:

MISCELLANEOUS

- ☐ Common Law/Statutory Arbitration
☐ Declaratory Judgment
☐ Mandamus
☐ Non-Domestic Relations
☐ Restraining Order
☐ Quo Warranto
☐ Replevin
☐ Other:

PROFESSIONAL LIABILITY

- ☐ Dental
☐ Legal
☐ Medical
☐ Other Professional:

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IN THE COURT OF COMMON PLEAS OF BEDFORD COUNTY PENNSYLVANIA

BEDFORD COUNTY
200 South Juliana Street
Third Floor, Suite 301
Bedford, PA 15522

Plaintiff,

v.

PURDUE PHARMA L.P.
One Stamford Forum
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Stamford, Connecticut 06901

AND

PURDUE PHARMA INC.
One Stamford Forum
201 Tresser Boulevard
Stamford, Connecticut 06901

AND

**THE PURDUE FREDERICK COMPANY,
INC.**
One Stamford Forum
201 Tresser Boulevard
Stamford, Connecticut 06901

AND

**: CIVIL ACTION – PRODUCT
: LIABILITY**

: JURY TRIAL DEMANDED

: NO. 180 - 2020

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CLERK OF ORPHAN'S COURT

TEVA PHARMACEUTICALS USA, INC.
1090 Horsham Road
North Wales, Pennsylvania 19454

AND

CEPHALON, INC.
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AND

JOHNSON & JOHNSON
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AND

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AND

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AND

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OF THE RAYMOND SACKLER FAMILY
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AND

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AND

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AND

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RITE AID CORPORATION

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AND

WAL-MART INC.,

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AND

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AND

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AND

VALUE DRUG
195 Theater Drive/ POB 1027
Duncansville, PA 166

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CLERK OF ORPHANS COURT

NOTICE

YOU HAVE BEEN SUED IN COURT. IF YOU WISH TO DEFEND AGAINST THE CLAIMS SET FORTH IN THE FOLLOWING PAGES, YOU MUST TAKE ACTION WITHIN TWENTY (20) DAYS AFTER THIS COMPLAINT AND NOTICE ARE SERVED, BY ENTERING A WRITTEN APPEARANCE PERSONALLY OR BY ATTORNEY AND FILING IN WRITING WITH THE COURT YOUR DEFENSES OR OBJECTIONS TO THE CLAIMS SET FORTH AGAINST YOU. YOU ARE WARNED THAT IF YOU FAIL TO DO SO THE CASE MAY PROCEED WITHOUT YOU AND A JUDGMENT MAY BE ENTERED AGAINST YOU BY THE COURT WITHOUT FURTHER NOTICE FOR ANY MONEY CLAIMED IN THE COMPLAINT OR FOR ANY OTHER CLAIM OR RELIEF REQUESTED BY THE PLAINTIFF. YOU MAY LOSE MONEY OR PROPERTY OR OTHER RIGHTS IMPORTANT TO YOU.

YOU SHOULD TAKE THIS PAPER TO YOUR LAWYER AT ONCE. IF YOU DO NOT HAVE A LAWYER, GO TO OR TELEPHONE THE OFFICE SET FORTH BELOW. THIS OFFICE CAN PROVIDE YOU WITH INFORMATION ABOUT HIRING A LAWYER.

IF YOU CANNOT AFFORD TO HIRE A LAWYER, THIS OFFICE MAY BE ABLE TO PROVIDE YOU WITH INFORMATION ABOUT AGENCIES THAT MAY OFFER LEGAL SERVICES TO ELIGIBLE PERSONS AT A REDUCED FEE OR NO FEE.

COURT ADMINISTRATOR
BEDFORD COUNTY COURTHOUSE
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BEDFORD, PA 15522
TELEPHONE NUMBER (814) 623-4812

COMPLAINT
TORT – PRODUCT LIABILITY

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Plaintiff, Bedford County, Pennsylvania (“Plaintiff”), by and through the undersigned attorneys, brings this action against the Defendants. Plaintiff asserts two categories of claims: (i) claims against the pharmaceutical manufacturers of prescription opioid drugs that engaged in a massive false marketing campaign to drastically expand the market for such drugs and their own market share and (ii) claims against entities in the supply chain that reaped enormous financial rewards by failing to monitor and restrict the improper distribution of those drugs.

INTRODUCTION

1. This case arises from the worst man-made epidemic in modern medical history—the misuse, abuse, and over-prescription of opioids.¹

2. The opioid crisis arose from pharmaceutical manufacturers’ deliberately deceptive marketing strategy to expand opioid use, together with pharmaceutical distributors’ equally deliberate efforts to evade restrictions on opioid distribution. Manufacturers and distributors alike acted without regard for the lives that would be trampled in pursuit of profit.

3. Since the push to expand prescription opioid use began in the late 1990s, the death toll has steadily climbed, with no sign of slowing. The number of opioid overdoses in the United States rose from 8,000 in 1999 to over 20,000 in 2009 and over 33,000 in 2015. In the twelve months that ended in September 2017, opioid overdoses claimed 45,000 lives.

4. From 1999 through 2016, overdoses killed more than 350,000 Americans. Over 200,000 of them—more than were killed in the Vietnam War—died from opioids prescribed by doctors to treat pain. These opioids include brand-name prescription medications such as

¹ Unless otherwise indicated, as used herein, the term “opioid” refers to the entire family of opiate drugs including natural, synthetic and semi-synthetic opiates.

OxyContin, Opana ER, Vicodin, Subsys, and Duragesic, as well as generics like oxycodone, hydrocodone, and fentanyl.

5. Most of the overdoses from non-prescription opioids are also directly related to prescription pills. Many opioid users, having become addicted to but no longer able to obtain prescription opioids, have turned to heroin. According to the American Society of Addiction Medicine, 80% of people who initiated heroin use in the past decade started with prescription opioids—which, at the molecular level and in their effect, closely resemble heroin. In fact, people who are addicted to prescription opioids are 40 times more likely to become addicted to heroin, and the Centers for Disease Control and Prevention (“CDC”) identifies addiction to prescription opioids as the strongest risk factor for heroin addiction.

6. As a result, in part, of the proliferation of opioid pharmaceuticals between the late 1990s and 2015, the life expectancy for Americans decreased for the first time in recorded history. Drug overdoses are now the leading cause of death for Americans under 50.

7. In the words of Robert Anderson, who oversees death statistics at the CDC, “I don’t think we’ve ever seen anything like this. Certainly not in modern times.”

8. On October 27, 2017, the President declared the opioid epidemic a public health emergency.

9. This suit takes aim at the two primary causes of the opioid crisis: (a) a marketing scheme involving the false and deceptive marketing of prescription opioids, which was designed to dramatically increase the demand for and sale of opioids and opioid prescriptions; and (b) a supply chain scheme, pursuant to which the various entities in the supply chain failed to design and operate systems to identify suspicious orders of prescription opioids, maintain effective

controls against diversion, and halt suspicious orders when they were identified, thereby contributing to the oversupply of such drugs and fueling an illegal secondary market.

10. On the marketing side, the crisis was precipitated by the defendants who manufacture, sell, and market prescription opioid painkillers (defined below as “Manufacturer Defendants”). Through a massive marketing campaign premised on false and incomplete information, the Manufacturer Defendants engineered a dramatic shift in how and when opioids are prescribed by the medical community and used by patients. The Manufacturer Defendants relentlessly and methodically, but untruthfully asserted that the risk of addiction was low when opioids were used to treat chronic pain, and overstated the benefits and trivialized the risk of the long-term use of opioids.

11. The Manufacturer Defendants’ goal was simple: to dramatically increase sales by convincing doctors to prescribe opioids not only for the kind of severe pain associated with cancer or short-term post-operative pain but also for common chronic pains, such as back pain and arthritis. They did this even though they knew that opioids were addictive and subject to abuse and that their other claims regarding the risks, benefits, and superiority of opioids for long-term use were untrue and unfounded.

12. The Manufacturer Defendants’ push to increase opioid sales worked. Through their publications and websites, and their endless stream of sales representatives, “education” programs, and other means, Manufacturer Defendants dramatically increased their sales of prescription opioids and reaped billions of dollars of profit as a result. Since 1999, the number of prescription opioids sold in the U.S. nearly quadrupled. In 2016, 289 million prescriptions for opioids were filled in the U.S.—enough to medicate every adult in America around the clock for a month.

13. Meanwhile, the Defendants made blockbuster profits. In 2012 alone, opioids generated \$8 billion in revenue for drug companies. By 2015, sales of opioids grew to approximately \$9.6 billion.

14. On the supply side, the crisis was fueled and sustained by those involved in the supply chain of opioids, including manufacturers, distributors, and pharmacies, who failed to maintain effective controls over the distribution of prescription opioids, and who instead have actively sought to evade such controls. These defendants have contributed substantially to the opioid crisis by selling and distributing far greater quantities of prescription opioids than they know could be necessary for legitimate medical uses, while failing to report, and to take steps to halt suspicious orders when they were identified, thereby exacerbating the oversupply of such drugs and fueling an illegal secondary market.

15. From the day they made the pills to the day those pills were consumed in our community, Manufacturer Defendants had control over the information regarding addiction they chose to spread and emphasize as part of their massive marketing campaign. By providing misleading information to doctors about addiction being rare and opioids being safe even in high doses, then pressuring doctors into prescribing their products by arguing, among other things, that no one should be in pain, Manufacturer Defendants created a population of addicted patients who sought opioids at never-before-seen rates. The scheme worked, and through it the Manufacturer Defendants caused their profits to soar as more and more people became dependent on opioids. Today, as many as 1 in 4 patients who receive prescription opioids long-term for chronic pain in a primary care setting struggles with addiction. And as of 2017, overdose death rates involving prescription opioids were five times higher than they were in 1999.

16. As millions of people became addicted to opioids, “pill mills,” self-styled as “pain clinics,” sprouted nationwide and rogue prescribers stepped in to supply prescriptions for non-medical use. These pill mills, typically under the auspices of licensed medical professionals, issue high volumes of opioid prescriptions under the guise of medical treatment. Prescription opioid pill mills and rogue prescribers cannot channel opioids for illicit use without the negligence, willful blindness, or knowing support of those in the supply chain.

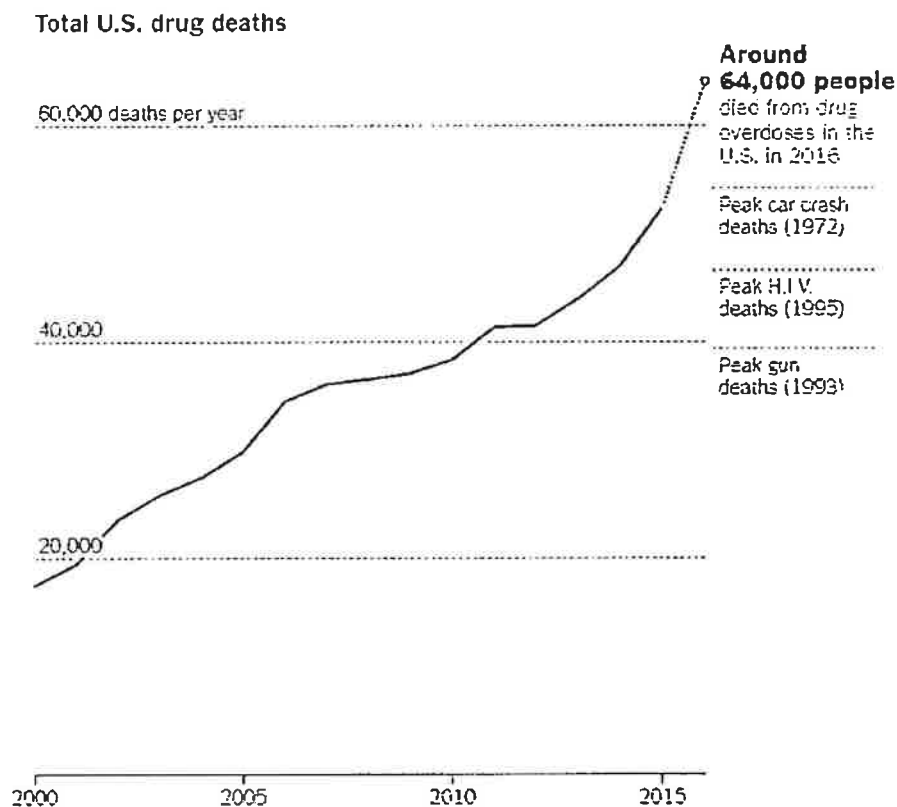
17. As a direct and foreseeable result of Defendants’ conduct, cities and counties across the nation, including Plaintiff, are now swept up in what the CDC has called a “public health epidemic” and what the U.S. Surgeon General has deemed an “urgent health crisis.” The increased volume of opioid prescribing correlates directly to skyrocketing addiction, overdose, and death; black markets for diverted prescription opioids; and a concomitant rise in heroin and fentanyl abuse by individuals who could no longer legally acquire—or simply could not afford—prescription opioids.

18. In 2016, approximately 64,000 people died from drug overdoses in the United States, more than the peak yearly death tolls from car crashes, HIV deaths, or gun deaths.² 66% of the drug overdose deaths in 2016 involved opioids, with the total deaths involving opioids taking

² Katz, Josh, *The First Count of Fentanyl Deaths in 2016: Up 540% in Three Years*, <https://www.nytimes.com/interactive/2017/09/02/upshot/fentanyl-drug-overdose-deaths.html> (published September 2, 2017, accessed October 27, 2017).

more lives than breast cancer.³ The total overdose deaths in 2016 were 10,000 more than in 2015.

The graph below shows the trend relating to overdose deaths since 2000:⁴



19. Thus, rather than compassionately helping patients in pain, this explosion in opioid use—and Defendants’ enrichment—has come at the expense of patients and Plaintiff and has caused ongoing harm and damages to Plaintiff. As the CDC director concluded in 2014: “We know of no other medication routinely used for a nonfatal condition that kills patients so frequently.”

³ Kounang, Nadia, *Opioids now kill more people than breast cancer*, <http://www.cnn.com/2017/12/21/health/drug-overdoses-2016-final-numbers/index.html> (accessed December 29, 2017).

⁴ Katz, Josh, *The First County of Fentanyl Deaths in 2016: Up 540% in Three Years*, *Supra*.

20. Defendants' conduct has had severe and far-reaching public health, social services, and criminal justice consequences, including the fueling of addiction and overdose from illicit drugs such as heroin. The costs are borne directly by Plaintiff and other governmental entities. These necessary and costly responses to the opioid crisis include, but are not limited to, the handling of emergency responses to overdoses, providing addiction treatment, handling opioid-related investigations, arrests, adjudications, and incarceration, treating opioid-addicted newborns in neonatal intensive care units, burying the dead, and placing of children in foster care.

21. The burdens imposed on Plaintiff are not the normal or typical burdens of government programs and services. Rather, these are extraordinary costs and losses that are directly caused by Defendants' illegal actions. Defendants' conduct has created a public nuisance and a blight. Governmental entities, and the services they provide their citizens, have been strained to the breaking point by this public health crisis.

22. Defendants have not changed their ways or corrected their past misconduct but instead are continuing to fuel the crisis.

23. Within the next hour, six Americans will die from opioid overdoses; two babies will be born dependent on opioids and begin to go through withdrawal, and drug manufacturers will earn over \$2.7 million from the sale of opioids.

24. Plaintiff has filed this suit to bring the devastating march of this epidemic to a halt and to hold Defendants responsible for the harm for which they are to blame.

JURISDICTION AND VENUE

25. This Court has jurisdiction over this action pursuant to Pa. Const. Art. V, §§ 4 and 42 Pa.C.S.A. § 761; 42 Pa.C.S.A. § 931(a); 42 Pa.C.S.A. § 5322; 16 Pa.C.S.A § 202 and 16 P.S. § 202.

26. Bedford County has standing to bring this lawsuit because 1 Pa.C.S.A § 1991 defines “Person” to include government entities, other than the Commonwealth itself.

27. This Court has personal jurisdiction over Defendants because they conduct business in Pennsylvania and Bedford County; purposefully direct or directed their negligent and injurious actions toward Pennsylvania and Bedford County; consensually submitted to the jurisdiction of Pennsylvania when obtaining a manufacturer or distributor license; have headquartered in Pennsylvania; have taken actions within Plaintiff’s jurisdictional boundaries that have foreseeably caused injury to Plaintiff, and have the requisite minimum contacts with Pennsylvania and Bedford County necessary to constitutionally permit the Court to exercise jurisdiction for adequate Due Process to Defendants.

28. Plaintiff has declared, *inter alia*, that opioid abuse, addiction, morbidity, and mortality has created a serious public health and safety crisis, and is a public nuisance, and that the diversion of legally produced controlled substances into the illicit market causes or contributes to this public nuisance.

29. Venue is proper in Bedford County pursuant to 42 Pa.C.S.A. § 931(c) and Pa.R.C.P. No. 2179(a)(4) as the transactions and occurrences that form the basis for this Complaint occurred in Bedford County.

30. This action is non-removable because no substantial federal question is presented and there is incomplete diversity of citizenship because Plaintiff and Defendant Janssen Pharmaceuticals, Inc. are residents of the Commonwealth of Pennsylvania. Additionally, multiple defendants are headquartered within the Commonwealth of Pennsylvania.

PARTIES

I. PLAINTIFF

31. Plaintiff Bedford County is a municipality organized and existing under the laws of the Commonwealth of Pennsylvania

32. Bedford County has a population of approximately 48,480 residents. The County provides a wide range of public services, including police and fire protection, emergency services, public health services, and services for families and children. Plaintiff has a duty to provide a wide range of services to its residents, including services for families and children, public health, public assistance, law enforcement, and emergency care.

33. Plaintiff brings this action on its own behalf and also as subrogee of its employees and residents and, as such, Plaintiff stands in the shoes of its subrogors, and is entitled to all the rights of its subrogors. In making the payments it has made on behalf of its employees and residents, Plaintiff did not act as a volunteer but rather acted under compulsion, for the protection of its interests, or as *parens patriae*.

II. DEFENDANTS

A. Manufacturer Defendants

34. As used herein, the term “Manufacturer Defendants” includes the Defendants identified in Section II(A).

35. At all relevant times, Manufacturer Defendants have manufactured, packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of the prescription opioid drugs. In addition, the Manufacturer Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

1. Purdue

36. Defendant Purdue Pharma L.P. ("PPLP") is a limited partnership organized under the laws of Delaware with its principal place of business in Stamford, Connecticut.

37. Defendant Purdue Pharma Inc. ("PPI") is a New York corporation with its principal place of business in Stamford, Connecticut. It is the general partner of PPLP.

38. Defendant The Purdue Frederick Company, Inc. ("PFC") is a New York corporation with its principal place of business in Stamford, Connecticut.

39. Defendant Rhodes Technologies ("Rhodes Tech") is a Delaware general partnership formed on April 12, 2005, with its principal place of business in Coventry, R.I.

40. Defendant Rhodes Technologies Inc. ("Rhodes Tech Inc.") is a Delaware corporation formed on January 28, 1999, with its principal place of business in Coventry, R.I. Rhodes Tech Inc. is a general partner of Rhodes Tech.

41. Defendant Rhodes Pharmaceuticals L.P. ("Rhodes Pharma") is a Delaware limited partnership formed on November 9, 2007, with its principal place of business in Coventry, R.I.

42. Defendant Rhodes Pharmaceuticals Inc. ("Rhodes Pharma Inc.") is a New York corporation formed on November 9, 2007. Rhodes Pharma Inc. is a general partner of Rhodes Pharma.

43. Defendant The P.F. Laboratories, Inc. ("PF Labs") is a New Jersey corporation with its principal place of business located in Totowa, New Jersey.

44. PPLP, PPI, PFC, Rhodes Tech, Rhodes Tech Inc., Rhodes Pharma, Rhodes Pharma Inc., and PF Labs are collectively referred to herein as "Purdue."

45. At all relevant times, Purdue has been beneficially owned, managed, and controlled by the families of Mortimer Sackler and Raymond Sackler, both of whom are now deceased.

46. Defendant Richard S. Sackler is a natural person residing in Travis County, Texas. He is a son of Raymond Sackler and, beginning in the 1990s, served as a member of the board of directors of Purdue and Purdue-related entities.

47. Defendant Jonathan D. Sackler is a natural person residing in Fairfield County, Connecticut. He is a son of Raymond Sackler and has been a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

48. Defendant Mortimer D.A. Sackler is a natural person residing in New York County, New York. He is the son of Mortimer Sackler and has been a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

49. Defendant Kathe A. Sackler is a natural person residing in Fairfield County, Connecticut. She is the daughter of Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

50. Defendant Ilene Sackler Lefcourt is a natural person residing in New York County, New York. She is the daughter of Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

51. Defendant Beverly Sackler is a natural person residing in Fairfield County, Connecticut. She is the widow of Raymond Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

52. Defendant Theresa Sackler is a natural person residing in New York County, New York. She is the widow of Mortimer Sackler and has served as a member of the board of directors of Purdue and Purdue-related entities since the 1990s.

53. Defendant David A. Sackler is a natural person residing in New York County, New York. He is the son of Richard Sackler (and the grandson of Raymond Sackler) and has served as a member of the board of directors of Purdue and Purdue-related entities since 2012.

54. Defendant Trust for the Benefit of Members of the Raymond Sackler Family (the “Raymond Sackler Trust”) is a trust of which Defendants Beverly Sackler, Richard S. Sackler, and/or Jonathan D. Sackler are trustees. It is the 50% direct or indirect beneficial owner of Purdue and the Purdue-related entities and the recipient of 50% of the profits from the sale of opioids by Purdue and Purdue-related entities.

55. Defendant Stuart D. Baker is a natural person residing in Suffolk County, New York. He has served as a senior executive of, and/or counsel to, Purdue, Purdue-related entities, and members of the Sackler families since the 1990s.

56. Purdue engaged in the manufacture, promotion, distribution, and sale of opioids nationally, in the Commonwealth of Pennsylvania, and in Plaintiff’s Community, including the following:

Purdue Opioids

Drug Name	Chemical Name	Schedule⁵
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⁵ Since passage of the Controlled Substances Act (“CSA”) in 1970, opioids have been regulated as controlled substances. As controlled substances, they are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the most dangerous. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally had been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence.

OxyContin	Oxycodone hydrochloride extended-release	Schedule II
MS Contin	Morphine sulfate extended-release	Schedule II
Dilaudid	Hydromorphone hydrochloride	Schedule II
Dilaudid-HP	Hydromorphone hydrochloride	Schedule II
Butrans	Buprenorphine	Schedule III
Hysingla ER	Hydrocodone bitrate	Schedule II
Targiniq ER	Oxycodone hydrochloride and naloxone hydrochloride	Schedule II

57. OxyContin is Purdue's largest-selling opioid. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between \$2.47 billion and \$3.1 billion, up four-fold from 2006 sales of \$800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (i.e., painkillers). OxyContin went from a mere \$49 million in its first full year on the market to \$1.6 billion in 2002.

58. In 2007, Purdue settled criminal and civil charges against it for misbranding OxyContin and agreed to pay the United States \$635 million – at the time, one of the largest settlements with a drug company for marketing misconduct. At the same time, Purdue executive officers Michael Friedman (the CEO), Howard Udell (Vice President and General Counsel), and Paul Goldenheim (Chief Medical Officer) pleaded guilty to criminal charges that they let Purdue deceive doctors and patients about its opioids. Pursuant to its settlement, Purdue operated under a Corporate Integrity Agreement with the Office of the Inspector General of the U.S. Department of Health and Human Services, which required the company and its officers and directors, *inter alia*, to ensure that its marketing was fair and accurate, and to monitor and report on its compliance with the Agreement. None of this stopped Purdue. In fact, Purdue continued to create the false perception that opioids were safe and effective for long term use, even after being caught, by using

unbranded marketing methods to circumvent the system. In short, despite the criminal convictions and the fine, Purdue continued to deceptively market and sell billions of dollars of opioids each year.

59. Purdue made thousands of payments to physicians nationwide, including in Pennsylvania, ostensibly for activities including participating in speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

60. Each of Richard S. Sackler, Jonathan D. Sackler, Mortimer D.A. Sackler, Kathe A. Sackler, Ilene Sackler Lefcourt, Beverly Sackler, Theresa Sackler, David A. Sackler, Raymond Sackler Trust (through its trustees), and Stuart D. Baker (collectively "Purdue-Related Additional Defendants") knowingly directed, aided, abetted, participated in, and benefitted from the wrongdoing of Purdue alleged herein.

2. Actavis

61. Defendant Allergan PLC is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis PLC acquired Allergan PLC in March 2015, and the combined company changed its name to Allergan PLC in January 2013. Defendant Actavis, Inc. was acquired by Watson Pharmaceuticals, Inc. in October 2012, and the combined company changed its name to Actavis, Inc. as of January 2013 and then Actavis PLC in October 2013. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California, and is a wholly-owned subsidiary of Allergan PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). Defendant Actavis Pharma, Inc. is registered to do business with the Ohio Secretary of State as a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc. Defendant Actavis LLC is a Delaware limited liability company with its principal place of business in Parsippany, New

Jersey. Each of these defendants and entities is owned by Defendant Allergan PLC, which uses them to market and sell its drugs in the United States. Collectively, these defendants and entities are referred to as “Actavis.”

62. Actavis manufactures or has manufactured the following drugs as well as generic versions of Kadian, Duragesic, and Opana in the United States:

Actavis Opioids

Product Name	Chemical Name	Schedule
Kadian	Morphine sulfate, extended-release	Schedule II
Norco	Hydrocodone bitartate and acetaminophen	Schedule II

63. Actavis made thousands of payments to physicians nationwide, including in Pennsylvania, ostensibly for activities including participating in speakers’ bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

3. Cephalon

64. Defendant Teva Pharmaceuticals USA, Inc. (“Teva USA”) is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA was in the business of selling generic opioids, including a generic form of OxyContin from 2005 to 2009. Teva USA is a wholly-owned subsidiary of Defendant Teva Pharmaceutical Industries, Ltd. (“Teva Ltd.”), an Israeli corporation (collectively “Teva”).

65. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon, Inc.

66. Teva USA and Cephalon, Inc. (collectively, "Cephalon") work together to manufacture, promote, distribute and sell both brand name and generic versions of opioids nationally and in Bedford County, including the following:

Cephalon Opioids

Drug Name	Chemical Name	Schedule
Actiq	Fentanyl citrate	Schedule II
Fentora	Fentanyl citrate	Schedule II

67. Teva USA was in the business of selling generic opioids, including a generic form of OxyContin beginning in 2005 nationally and in Bedford County.

68. From 2000 forward, Cephalon has made thousands of payments to physicians nationwide, including in Pennsylvania, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, many of whom were not oncologists and did not treat cancer pain, but in fact to deceptively promote and maximize the use of opioids.

4. Janssen

69. Defendant Johnson & Johnson ("J&J") is a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

70. Defendant Janssen Pharmaceuticals, Inc. ("Janssen Pharmaceuticals") is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey, and is a wholly-owned subsidiary of J&J. Janssen Pharmaceuticals was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc.

71. Defendant Noramco, Inc. (“Noramco”) is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J and its manufacturer of active pharmaceutical ingredients until July 2016 when J&J sold its interests to SK Capital.

72. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. (“OMP”), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

73. Defendant Janssen Pharmaceutica, Inc. (“Janssen Pharmaceutica”), now known as Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

74. J&J, Janssen Pharmaceuticals, Noramco, OMP, and Janssen Pharmaceutica (collectively, “Janssen”) are or have been engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in Bedford County. Among the drugs Janssen manufactures or manufactured are the following:

Janssen Opioids

Drug Name	Chemical Name	Schedule
Duragesic	Fentanyl	Schedule II
Nucynta ⁶	Tapentadol extended release	Schedule II
Nucynta ER	Tapentadol	Schedule II

⁶ Depomed, Inc. acquired the rights to Nucynta and Nucynta ER from Janssen in 2015.

75. Together, Nucynta and Nucynta ER accounted for \$172 million in sales in 2014. Prior to 2009, Duragesic accounted for at least \$1 billion in annual sales.

76. Janssen, like many other companies, has a corporate code of conduct, which clarifies the organization's mission, values and principles. Janssen's employees are required to read, understand and follow its Code of Conduct for Health Care Compliance. J&J imposes this code of conduct on Janssen as a pharmaceutical subsidiary of J&J. Documents posted on J&J's and Janssen's websites confirm J&J's control of the development and marketing of opioids by Janssen. Janssen's website "Ethical Code for the Conduct of Research and Development," names only J&J and does not mention Janssen anywhere within the document. The "Ethical Code for the Conduct of Research and Development" posted on the Janssen website is J&J's company-wide Ethical Code, which it requires all of its subsidiaries to follow.

77. The "Every Day Health Care Compliance Code of Conduct" posted on Janssen's website is a J&J company-wide document that describes Janssen as one of the "Pharmaceutical Companies of Johnson & Johnson" and as one of the "Johnson & Johnson Pharmaceutical Affiliates." It governs how "[a]ll employees of Johnson & Johnson Pharmaceutical Affiliates," including those of Janssen, "market, sell, promote, research, develop, inform and advertise Johnson & Johnson Pharmaceutical Affiliates' products." All Janssen officers, directors, employees, sales associates must certify that they have "read, understood and will abide by" the code. The code governs all of the forms of marketing at issue in this case.

78. J&J controls the sale and development of Janssen's drugs, J&J handles Jansen's dealings with the FDA concerning Janssen's drugs, and Janssen's profits inure to J&J's benefit.

79. Janssen made thousands of payments to physicians nationwide, including in Pennsylvania, ostensibly for activities including participating on speakers' bureaus, providing

consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

5. Endo

80. Defendant Endo Health Solutions Inc. (“EHS”) is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

81. Defendant Endo Pharmaceuticals, Inc. (“EPI”) is a wholly-owned subsidiary of EHS and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania.

82. Defendant Par Pharmaceutical, Inc. is a New York corporation with its principal place of business located in Chestnut Ridge, New York. Par Pharmaceutical, Inc. is a wholly-owned subsidiary of Defendant Par Pharmaceutical Companies, Inc., a Delaware corporation with its principal place of business in Chestnut Ridge, New York. Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. are referred to collectively herein as “Par Pharmaceutical.”

83. EHS, EPI, and Par Pharmaceutical, and their DEA registrant subsidiaries and affiliates (collectively, “Endo”), manufacture, promote, distribute and sell opioids throughout the United States and in Bedford County, including the following:

Endo Opioids

Drug Name	Chemical Name	Schedule
Opana ER	Oxymorphone hydrochloride extended release	Schedule II
Opana	Oxymorphone hydrochloride	Schedule II
Percodan	Oxymorphone hydrochloride and aspirin	Schedule II
Percocet	Oxymorphone hydrochloride and acetaminophen	Schedule II
Generic	Oxycodone	Schedule II

Generic	Oxymorphone	Schedule II
Generic	Hydromorphone	Schedule II

84. Endo made thousands of payments to physicians nationwide, including in Pennsylvania, ostensibly for activities including participating on speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

85. Opioids made up roughly \$403 million of Endo's overall revenues of \$3 billion in 2012, accounting for over 10% of Endo's total revenue; Opana ER yielded revenue of \$1.15 billion from 2010 to 2013. Endo also manufactures and sells generic opioids, both directly and through its subsidiary, Qualitest Pharmaceuticals, Inc., including generic oxycodone, oxymorphone, hydromorphone, and hydrocodone products.

86. The Food and Drug Administration ("FDA") requested that Endo remove Opana ER from the market in June 2017. The FDA relied on post-marketing data in reaching its conclusion based on the risk of abuse.

6. Insys

87. Insys Therapeutics, Inc. is a Delaware corporation with its principal place of business in Chandler, Arizona.

88. Insys is or has been engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in Bedford County. Among the drugs Insys manufactures or manufactured are the following:

Insys Opioids

Product Name	Chemical Name	Schedule
Subsys	Fentanyl	Schedule II

89. Insys made thousands of payments to physicians nationwide, including in Pennsylvania, ostensibly for activities including participating in speakers' bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact, the payments were made to deceptively promote and maximize the use of opioids.

90. Insys's principal product and source of revenue is Subsys, a transmucosal immediate-release formulation (TIRF) of fentanyl, contained in a single-dose spray device intended for oral, under the tongue administration. Subsys was approved by the FDA solely for the treatment of breakthrough cancer pain.

91. In 2016, Insys made approximately \$330 million in net revenue from Subsys. Insys promotes, sells, and distributes Subsys throughout the United States, and in Bedford County.

92. Insys's founder and owner were recently arrested and charged, along with other Insys executives, with multiple felonies in connection with an alleged conspiracy to bribe practitioners to prescribe Subsys and defraud insurance companies. Other Insys executives and managers were previously indicted.

7. Amneal Pharmaceuticals

93. Defendant AMNEAL PHARMACEUTICALS, LLC is a Delaware limited liability company registered to do business in Pennsylvania with its headquarters office located in Bridgewater, New Jersey.

94. Defendant AMNEAL PHARMACEUTICALS OF NEW YORK, LLC is a Delaware limited liability company that is authorized to do business in Pennsylvania with its principal place of business in New Jersey. Defendant AMNEAL PHARMACEUTICALS OF NEW YORK, LLC is a subsidiary of Defendant AMNEAL PHARMACEUTICALS, LLC.

95. Defendants AMNEAL PHARMACEUTICALS, LLC and AMNEAL PHARMACEUTICALS OF NEW YORK, LLC are collectively referred to as “AMNEAL”. Defendant AMNEAL manufactures, markets, sells and distributes pharmaceutical drugs throughout the United States and Bedford County, including opioid medications.

96. Defendant AMNEAL, at all relevant times manufactured, promoted, sold and/or distributed prescription drugs, including opioids in Plaintiff’s community, throughout Pennsylvania and throughout the United States. Defendant AMNEAL’s opioid products include Acetaminophen/Codeine Phosphate USP Tablet, Buprenorphine & Naloxone Tablet, Hydrocodone/APAP Tablet, Hydrocodone/Tbuprofen Tablet, Morphine Sulfate ER Capsule, Oxycodone HCl ER Tablet, Oxycodone HCl USP Tablet, Oxycodone/APAP USP Tablet, Oxymorphone⁷ HCl ER Tablet, Tramadol HCl USP Tablet, and Tramadol/APAP USP Tablet.

97. Defendant AMNEAL took advantage of the lucrative market for chronic pain patients and developed a well-funded marketing scheme based on deceptive practices. Defendants spread their false and deceptive statements by marketing their branded opioids directly to physicians and their patients nationally and in Plaintiff’s community.

8. *Mallinckrodt*

98. Defendant Mallinckrodt plc is an Irish public limited company with its headquarters in Staines-Upon-Thames, Surrey, United Kingdom. Mallinckrodt plc was incorporated in January 2013 for the purpose of holding the pharmaceuticals business of Covidien plc, which was fully transferred to Mallinckrodt plc in June 2013. Mallinckrodt plc also operates under the registered business name Mallinckrodt Pharmaceuticals, with its U.S. headquarters in Hazelwood, Missouri.

⁷ Oxymorphone is the active ingredient in Opana, which in 2017 the FDA requested Endo remove from the market due to the risks of abuse. <https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm562401.htm>

99. Defendant Mallinckrodt LLC is a Delaware corporation with its principal place of business in Hazelwood, Missouri.

100. Defendant SpecGx LLC is a Delaware limited liability company with its principal place of business in Clayton, Missouri and a wholly-owned subsidiary of Mallinckrodt plc.

101. Mallinckrodt plc, Mallinckrodt LLC, and SpecGx LLC and their DEA registrant subsidiaries and affiliates (together, "Mallinckrodt") manufacture, market, sell and distribute pharmaceutical drugs throughout the United States and in Bedford County.

102. Mallinckrodt is the largest U.S. supplier of opioid pain medications and among the top ten generic pharmaceutical manufacturers in the United States based on prescriptions.

103. Mallinckrodt manufactures and markets two branded opioids: Exalgo, which is extended-release hydromorphone, sold in 8, 12, 16, and 32 mg dosage strengths, and Roxicodone, which is oxycodone, sold in 15 and 30 mg dosage strengths. In 2009, Mallinckrodt Inc., a subsidiary of Covidien plc, acquired the U.S. rights to Exalgo. The FDA approved Exalgo for treatment of chronic pain in 2012. Mallinckrodt further expanded its branded opioid portfolio in 2012 by purchasing Roxicodone from Xanodyne Pharmaceuticals. In addition, Mallinckrodt developed Xartemis XR, an extended-release combination of oxycodone and acetaminophen, which the FDA approved in March 2014, and which Mallinckrodt has since discontinued. Mallinckrodt promoted its branded opioid products with its own direct sales force.

104. While it has sought to develop its branded opioid products, Mallinckrodt has long been a leading manufacturer of generic opioids. Mallinckrodt estimated that in 2015 it received approximately 25% of the DEA's entire annual quota for controlled substances that it manufactures. Mallinckrodt also estimated that its generics claimed an approximately 23% market share of DEA Schedules II and III opioid and oral solid dose medications.

105. Mallinckrodt operates a vertically integrated business in the United States: (1) importing raw opioid materials, (2) manufacturing generic opioid products, primarily at its facility in Hobart, New York, and (3) marketing and selling its products to drug distributors, specialty pharmaceutical distributors, retail pharmacy chains, pharmaceutical benefit managers that have mail-order pharmacies, and hospital buying groups.

106. Among the drugs Mallinckrodt manufactures or has manufactured are the following:

Mallinckrodt Opioids

Product Name	Chemical Name	Schedule
Exalgo	Hydromorphone hydrochloride, extended release	Schedule II
Roxicodone	Oxycodone hydrochloride	Schedule II
Xartemis XR	Oxycodone hydrochloride and acetaminophen	Schedule II
Methadose	Methadone hydrochloride	Schedule II
Generic	Morphine sulfate, extended release	Schedule II
Generic	Morphine sulfate oral solution	Schedule II
Generic	Fentanyl transdermal system	Schedule II
Generic	Oral transmucosal fentanyl citrate	Schedule II
Generic	Oxycodone and acetaminophen	Schedule II
Generic	Hydrocodone bitartrate and acetaminophen	Schedule II
Generic	Hydromorphone hydrochloride	Schedule II
Generic	Hydromorphone hydrochloride, extended release	Schedule II
Generic	Naltrexone hydrochloride	unscheduled
Generic	Oxymorphone hydrochloride	Schedule II
Generic	Methadone hydrochloride	Schedule II
Generic	Oxycodone hydrochloride	Schedule II

Product Name	Chemical Name	Schedule
Generic	Buprenorphine and naloxone	Schedule III

107. Mallinckrodt made thousands of payments to physicians nationwide, including in Pennsylvania, ostensibly for activities including participating in speakers bureaus, providing consulting services, assisting in post-marketing safety surveillance and other services, but in fact to deceptively promote and maximize the use of opioids.

9. “Manufacturer Defendants” Defined

108. Collectively, Purdue, Purdue-Related Additional Defendants, Actavis, Cephalon, Janssen, Endo, Insys, Amneal Pharmaceuticals, and Mallinckrodt are referred to as “Manufacturer Defendants.”

B. Distributor Defendants

109. As used herein, the term “Distributor Defendants” includes the Defendants identified in Section II(B).

110. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce the prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants universally failed to comply with federal and/or state law. The Distributor Defendants are engaged in “wholesale distribution,” as defined under state and federal law. Plaintiff alleges the unlawful conduct by the Distributor Defendants is a substantial cause for the excessive volume of prescription opioids plaguing Plaintiff’s Community and of the diversion of prescription opioids into Plaintiff’s Community.

1. Cardinal

111. Cardinal Health, Inc. (“Cardinal”) is an Ohio Corporation with its principal place of business in Dublin, Ohio.

112. Cardinal distributes pharmaceuticals to retail pharmacies and institutional providers in all 50 states, including in Pennsylvania and Bedford County.

113. Cardinal describes itself as a “global, integrated health care services and products company,” and it is the fifteenth largest company by revenue in the U.S., with annual revenue of \$121 billion in 2016.

114. Cardinal has been licensed as a wholesale distributor of dangerous drugs in Pennsylvania since 1990.

115. Based on Defendant Cardinal’s own estimates, one of every six pharmaceutical products dispensed to United States patients travels through the Cardinal Health network.

2. Anda

116. Defendant Anda, Inc. (“Anda”), is a Florida corporation with its principal office located in Olive Branch, Mississippi. Through its various DEA registrant subsidiaries and affiliated entities, Anda is the fourth largest distributor of generic pharmaceuticals in the United States. In October 2016, Defendant Teva USA acquired Anda for \$500 million in cash. At all times relevant to this Complaint, Anda distributed prescription opioids throughout the United States, including in Pennsylvania and Bedford County.

3. McKesson

117. Defendant McKesson Corporation (“McKesson”) is a Delaware corporation with its principal place of business in San Francisco, California.

118. McKesson is fifth on the list of Fortune 500 companies, ranking immediately after Apple and ExxonMobil, with an annual revenue of \$191 billion in 2016. McKesson is a wholesaler

of pharmaceutical drugs that distributes opioids throughout the country, including Pennsylvania and Bedford County.

119. In January 2017, McKesson paid a record \$150 million to resolve an investigation by the U.S. Department of Justice (“DOJ”) for failing to report suspicious orders of certain drugs, including opioids. In addition to the monetary penalty, the DOJ required McKesson to suspend sales of controlled substances from distribution centers in Ohio, Florida, Michigan, and Colorado. The DOJ described these “staged suspensions” as “among the most severe sanctions ever agreed to by a [DEA] registered distributor.”

4. CVS

120. Defendant CVS Health Corporation (“CVS”) is a Delaware corporation with its principal place of business in Rhode Island. CVS, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor. CVS also operates retail stores that sell prescription medicines including opioids.

121. At all times relevant to this Complaint, CVS distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in Pennsylvania and Bedford County.

5. Rite-Aid

122. Defendant Rite Aid of Maryland, Inc., dba Rite Aid Mid-Atlantic Customer Support Center, Inc., is a Maryland corporation with its principal office located in Camp Hill, Pennsylvania.

123. Defendant Rite Aid Corporation is a Delaware corporation with its principal offices located in Camp Hill, Pennsylvania. Together, Rite Aid of Maryland, Inc. and Rite Aid Corporation are referred to as “Rite Aid.”

124. Rite Aid, through its various DEA registered subsidiaries and affiliated entities, conducts business as a licensed wholesale distributor.

125. Rite-Aid also operates retail stores, which sell prescription medicines, including opioids.

126. At all times relevant to this Complaint, Rite Aid, through its various DEA registered subsidiaries and affiliated entities, distributed prescription opioids and engaged in the retail selling of opioids throughout the United States, including in Pennsylvania and Bedford County.

127. Eckerd Corporation was an American drug store chain that was headquartered in Largo, Florida. Rite Aid Corporation acquired Eckerd Pharmacy stores in June of 2007 at which time Rite Aid announced that the two chains would be converted to the Rite Aid name and all remaining Eckerd stores were converted to Rite Aid by the end of September 2007. Eckerd Corporation, at all times relevant hereto, was involved in the regulated distribution of opioid medications to Eckerd stores and Rite Aid's retail pharmacies located in Plaintiff's community. All of the Eckerd Corporation retail pharmacies will hereinafter be included in and also referred to as Defendant "Rite Aid".

6. Wal-Mart

128. Defendant Wal-Mart Inc., formerly known as Wal-Mart Stores, Inc. ("Wal-Mart"), is a Delaware corporation with its principal place of business in Arkansas. Wal-Mart, through its various DEA, registered affiliated entities, conducts business as a licensed wholesale distributor. At all times relevant to this Complaint, Wal-Mart distributed prescription opioids and engaged in retail selling of opioids throughout the United States, including in Pennsylvania and Bedford County.

7. *Rochester Drug Co-Operative*

129. Defendant Rochester Drug Co-Operative, Inc. (“RDC”) Is a New York corporation and is authorized to do business in Pennsylvania, with its principal place of business located in Rochester, New York.

130. At all times relevant hereto, RDC distributed prescription opioids throughout Pennsylvania and in Plaintiff’s community.

131. RDC is among the ten largest wholesalers in the United States with an estimated annual revenue of \$2 billion.

8. *Value Drug*

132. Defendant Value Drug Company (“Value Drug”) is a Pennsylvania corporation with its principal place of business in Duncansville, Pennsylvania. Value Drug through its various DEA registered subsidiaries and affiliated entities conduct business as a licensed wholesale distributor.

133. At all times relevant to this Complaint, Value Drug distributed prescription opioids throughout the United States, including Pennsylvania and Bedford County.

134. Value Drug paid \$4,000,000 in settlement claims due to failure to report suspicious orders of Oxycodone to pharmacies in Maryland and Pennsylvania in 2014.

9. *“Distributor Defendants” Defined*

135. Cardinal, McKesson, Rochester Drug Co-Operative, Anda, Value Drug, and the National Retail Pharmacies are collectively referred to as the “Distributor Defendants.”

10. *“National Retail Pharmacies” Defined*

136. Collectively, Defendants CVS, Rite Aid, Wal-Mart are referred to as “National Retail Pharmacies.”

C. Agency and Authority

137. All of the actions described in this Complaint are part of, and in furtherance of, the unlawful conduct alleged herein, and were authorized, ordered, and/or done by Defendants' officers, agents, employees, or other representatives while actively engaged in the management of Defendants' affairs within the course and scope of their duties and employment, and/or with Defendants' actual, apparent, and/or ostensible authority.

D. Affiliates of Named Defendants

138. Defendants include the above-referenced entities as well as their predecessors, successors, affiliates, subsidiaries, partnerships and divisions to the extent that they are engaged in the manufacture, promotion, distribution, sale, and/or dispensing of opioids.

FACTS COMMON TO ALL CLAIMS

I. OPIOIDS AND THEIR EFFECTS

139. The term "opioid" refers to a class of drugs that bind with opioid receptors in the brain and includes natural, synthetic, and semi-synthetic opioids. Natural opioids are derived from the opium poppy. Generally used to treat pain, opioids produce multiple effects on the human body, the most significant of which are analgesia, euphoria, and respiratory depression.

140. The medicinal properties of opioids have been recognized for millennia—as well as their potential for abuse and addiction. The opium poppy contains various opium alkaloids, three of which are used in the pharmaceutical industry today: morphine, codeine, and thebaine. Early use of opium in Western medicine was with a tincture of opium and alcohol called laudanum, which contains all of the opium alkaloids and is still available by prescription today. Chemists first isolated the morphine and codeine alkaloids in the early 1800s.

141. In 1827, the pharmaceutical company Merck began large-scale production and commercial marketing of morphine. During the American Civil War, field medics commonly used

morphine, laudanum, and opium pills to treat the wounded, and many veterans were left with morphine addictions. By 1900, an estimated 300,000 people were addicted to opioids in the United States, and many doctors prescribed opioids solely to prevent their patients from suffering withdrawal symptoms. The nation's first Opium Commissioner, Hamilton Wright, remarked in 1911, "The habit has this nation in its grip to an astonishing extent. Our prisons and our hospitals are full of victims of it, it has robbed ten thousand businessmen of moral sense and made them beasts who prey upon their fellows ... it has become one of the most fertile causes of unhappiness and sin in the United States."

142. Pharmaceutical companies tried to develop substitutes for opium and morphine that would provide the same analgesic effects without the addictive properties. In 1898, Bayer Pharmaceutical Company began marketing diacetylmorphine (obtained from acetylation of morphine) under the trade name "Heroin." Bayer advertised heroin as a non-addictive cough and cold remedy suitable for children, but as its addictive nature became clear, heroin distribution in the U.S. was limited to prescription only in 1914 and then banned altogether a decade later.

143. Although heroin and opium became classified as illicit drugs, there is little difference between them and prescription opioids. Prescription opioids are synthesized from the same plant as heroin, have similar molecular structures, and bind to the same receptors in the human brain.

144. Due to concerns about their addictive properties, prescription opioids have usually been regulated at the federal level as Schedule II controlled substances by the U.S. Drug Enforcement Administration ("DEA") since 1970.

145. Throughout the twentieth century, pharmaceutical companies continued to develop prescription opioids like Percodan, Percocet, and Vicodin, but these opioids were generally produced in combination with other drugs, with relatively low opioid content.

146. In contrast, OxyContin, the product whose launch in 1996 ushered in the modern opioid epidemic, is pure oxycodone. Purdue initially made it available in the following strengths: 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, 80 mg, and 160 mg. The weakest OxyContin delivers as much narcotic as the strongest Percocet, and some OxyContin tablets delivered sixteen times that.

147. Medical professionals describe the strength of various opioids in terms of morphine milligram equivalents (“MME”). According to the CDC, doses at or above 50 MME/day double the risk of overdose compared to 20 MME/day, and one study found that patients who died of opioid overdose were prescribed an average of 98 MME/day.

148. Different opioids provide varying levels of MMEs. For example, just 33 mg of oxycodone provides 50 MME. Thus, at OxyContin’s twice-daily dosing, the 50 MME/day threshold is nearly reached by a prescription of 15 mg twice daily. One 160 mg tablet of OxyContin, which Purdue took off the market in 2001, delivered 240 MME.

149. The wide variation in the MME strength of prescription opioids renders misleading any effort to capture “market share” by the number of pills or prescriptions attributed to Purdue or other manufacturers. Purdue, in particular, focuses its business on branded, highly potent pills, causing it to be responsible for a significant percentage of the total amount of MME in circulation, even though it currently claims to have a small percent of the market share in terms of pills or prescriptions.

150. Fentanyl is a synthetic opioid that is 100 times stronger than morphine and 50 times stronger than heroin. First developed in 1959, fentanyl is showing up more and more often in the market for opioids created by Manufacturer Defendants' promotion, with particularly lethal consequences.

151. The effects of opioids vary by duration. Long-acting opioids, such as Purdue's OxyContin and MS Contin, Janssen's Nucynta ER and Duragesic, Endo's Opana ER, and Actavis's Kadian, are designed to be taken once or twice daily and are purported to provide continuous opioid therapy for, in general, 12 hours. Short-acting opioids, such as Cephalon's Actiq and Fentora, are designed to be taken in addition to long-acting opioids to address "episodic pain" (also referred to as "breakthrough pain") and provide fast-acting, supplemental opioid therapy lasting approximately 4 to 6 hours. Still, other short-term opioids, such as Insys's Subsys, are designed to be taken in addition to long-acting opioids to specifically address breakthrough cancer pain, excruciating pain suffered by some patients with end-stage cancer. The Manufacturer Defendants promoted the idea that pain should be treated by taking long-acting opioids continuously and supplementing them by also taking short-acting, rapid-onset opioids for episodic or "breakthrough" pain.

152. Patients develop tolerance to the analgesic effect of opioids relatively quickly. As tolerance increases, a patient typically requires progressively higher doses in order to obtain the same perceived level of pain reduction. The same is true of the euphoric effects of opioids—the "high." However, opioids depress respiration, and at very high doses can, and often do, arrest respiration altogether. At higher doses, the effects of withdrawal are more severe. Long-term opioid use can also cause hyperalgesia, a heightened sensitivity to pain.

153. Discontinuing opioids after more than just a few weeks of therapy will cause most patients to experience withdrawal symptoms. These withdrawal symptoms include severe anxiety, nausea, vomiting, headaches, agitation, insomnia, tremors, hallucinations, delirium, pain, and other serious symptoms, which may persist for months after the complete withdrawal from opioids, depending on how long the opioids were used.

154. As a leading pain specialist doctor put it, the widespread, long-term use of opioids “was a *de facto* experiment on the population of the United States. It wasn’t randomized, it wasn’t controlled, and no data was collected until they started gathering death statistics.”

II. THE RESURGENCE OF OPIOID USE IN THE UNITED STATES

A. The Sackler Family Integrated Advertising and Medicine

155. Given the history of opioid abuse in the U.S. and the medical profession’s resulting wariness, the commercial success of the Manufacturer Defendants’ prescription opioids would not have been possible without a fundamental shift in prescribers’ perception of the risks and benefits of long-term opioid use.

156. As it turned out, Purdue was uniquely positioned to execute just such a maneuver, thanks to the legacy of a man named Arthur Sackler. The Sackler family is the sole owner of Purdue and one of the wealthiest families in America, with an estimated net worth of \$13 billion as of 2016. All of Purdue’s profits go to Sackler family trusts and entities and, through them, to members of the Sackler families.

157. Arthur Sackler was both a psychiatrist and a marketing executive, and, by many accounts, a brilliant and driven man. He pursued two careers simultaneously, as a psychiatrist at Creedmoor State Hospital in New York and the president of an advertising agency called William Douglas McBedford. He pioneered both print advertising in medical journals and promotion through physician “education” in the form of seminars and continuing medical education (“CME”)

courses. He also understood the persuasive power of recommendations from fellow physicians and did not hesitate to manipulate information when necessary. For example, one promotional brochure produced by his firm for Pfizer showed business cards of physicians from various cities as if they were testimonials for the drug, but when a journalist tried to contact these doctors, he discovered that they did not exist.

158. Arthur Sackler revolutionized medical marketing in the 1950s and '60s by creating the very marketing ploys his family later used to perpetuate the massive fraud alleged in this action. In striving to make Pfizer (with its blockbuster drug, valium) a household name among physicians, Arthur Sackler recognized that “selling new drugs requires a seduction of not just the patient but the doctor who writes the prescription,” and he maximized influence over physician prescribing by developing the following marketing ploys to disseminate pharmaceutical messaging under the guise of science and truth:

- a. contacting prescribers directly with a variety of perks, benefits and even job offers;
- b. publishing seemingly neutral articles in medical journals, citing scientific studies (frequently underwritten by the pharmaceutical companies whose products he was marketing);
- c. marketing illnesses (i.e., lamenting and marketing the under-treatment of purported illnesses and the corresponding under-utilization of drugs he was promoting);
- d. paying prominent physicians to endorse his products; and
- e. funding CMEs, controlling the messaging of key opinion leaders, and maximizing influence over physician prescribing practices.

159. In the 1960s Arthur Sackler made Valium into the first \$100-million drug, so popular it became known as “Mother’s Little Helper.” His expertise as a psychiatrist was one of

the keys to his success. When Arthur's client, Roche, developed Valium, it already had a similar drug, Librium, another benzodiazepine, on the market for the treatment of anxiety. So Arthur invented a condition he called "psychic tension"—essentially stress—and pitched Valium as the solution. The campaign, for which Arthur was compensated based on the volume of pills sold, was a remarkable success.

160. Arthur Sackler created not only the advertising for his clients but also the vehicle to bring their advertisements to doctors—a biweekly newspaper called the *Medical Tribune*, which was distributed for free to doctors nationwide. Arthur also co-founded a company called IMS Health ("IMS") (which is now part of IQVIA), which monitors prescribing practices of every doctor in the U.S. and sells the data to pharmaceutical companies like Manufacturer Defendants, who utilize it to target and tailor their sales pitches to individual physicians.

161. In marketing tranquilizers Librium and Valium, Arthur Sackler broadened his customer base to potentially include everyone. For example, one campaign encouraged doctors to prescribe Valium to people with no psychiatric symptoms whatsoever, urging doctors to "consider the usefulness of Valium" in patients with *no* demonstrable pathology. Such marketing-led one physician, writing in the journal *Psychosomatics* in 1965, to ask, "When do we *not* use this drug?"

162. As the line between medical education and medical marketing became deliberately blurred, Valium became the pharmaceutical industry's first hundred-million-dollar, and then the billion-dollar, drug. For his design and creation of these medical marketing strategies, he was posthumously inducted into the Medical Advertising Hall of Fame, but, as succinctly put by Allen Frances, the former chair of psychiatry at Duke University School of Medicine: "Most of the questionable practices that propelled the pharmaceutical industry into the scourge it is today can be attributed to Arthur Sackler."

163. In other precursors of the current crisis, Arthur Sackler promoted these drugs despite the lack of any studies of their addictive potential. Additionally, he started *Medical Tribune*, despite concerns that a pharmaceutical advertiser should not be publishing a medical periodical directed at doctors. He paid Key Opinion Leaders (“KOLs”), including, for example, Henry Welch (then chief of FDA’s antibiotics division), almost \$300,000 in exchange for his help in promoting pharmaceutical drugs. By the 1970s, doctors were prescribing more than 100 million tranquilizer prescriptions annually, creating what Sen. Edward Kennedy called “a nightmare of dependence and addiction.”

B. Purdue and the Development of OxyContin

164. In 1952, Arthur Sackler and his two brothers, Mortimer Sackler and Raymond Sackler, purchased what was then a small patent-medicine company called the Purdue Frederick Company (“PF Co.”).

165. PF Co. had been formed in 1892 by Dr. John Purdue Gray and George Frederick Bingham and incorporated in New York on June 29, 1911.

166. After Arthur’s death, Mortimer and Raymond bought out his share. Since that time, PF Co. and all Purdue-related companies have all been owned and controlled by the Raymond Sackler Family and the Mortimer Sackler Family.

167. PF Co. is no longer an active New York corporation, having been merged into Defendant PF Labs on May 7, 2004.

168. At all relevant times, PF Co. and PF Labs have been beneficially owned by the Sackler Families and controlled by them through Defendant Sackler Family members.

169. After the Sacklers acquired PF Co. in 1952, they sold products ranging from earwax remover to antiseptic, and it became a profitable business. As an advertising executive, Arthur Sackler was not involved, on paper at least, in running the family business, which would have been

a conflict of interest. Raymond Sackler became Purdue's head executive, while Mortimer Sackler ran Purdue's UK affiliate.

170. Beginning in the 1980s PF Co. and its associated companies engaged in the business of designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling or distributing opioids throughout the United States.

171. In the 1980s, the Sacklers, through a UK company they owned, acquired a Scottish drug producer that had developed a sustained-release technology suitable for morphine. They marketed this extended-release morphine as MS Contin, and it quickly became their bestseller. As the patent expiration for MS Contin loomed, they searched for a drug to replace it. Around that time, Raymond's oldest son, Defendant Richard Sackler, who was also a trained physician, became more involved in the management of the family business. Richard had grand ambitions for the company. According to a long-time Purdue sales representative, "Richard really wanted Purdue to be big—I mean *really* big." Richard believed Purdue should develop another use for its "Contin" timed-release system.

172. OxyContin was created by PF Co., but responsibility for designing, testing, manufacturing, labeling, advertising, promoting, marketing, selling, and distributing OxyContin and other opioid products was shared among PF Co., Purdue, PF Labs, and other Purdue-related companies.

173. At relevant times, OxyContin was manufactured by PF Labs.

174. In 1990, Purdue's vice president of clinical research, Robert Kaiko, sent a memo to Richard and other executives recommending that the company work on a pill containing oxycodone. At the time, oxycodone was perceived as less potent than morphine, largely because it was most commonly prescribed as Percocet, a relatively weak oxycodone-acetaminophen

combination pill, or Percodan, where it was blended with aspirin. By contrast, the oxycodone pill developed by Purdue—OxyContin—was pure oxycodone in a time-release formula similar to MS Contin, and it was more potent than morphine. Purdue also decided to produce pills with as much as 160 milligrams of oxycodone, far in excess of any other prescription opioid.

175. MS Contin was not only approaching patent expiration but had always been limited by the stigma associated with morphine. Oxycodone did not have that problem, and what's more, it was sometimes mistakenly called "oxycodine," which also contributed to the perception of relatively lower potency, because codeine is weaker than morphine. Purdue acknowledged using this false perception to its advantage when it later pled guilty to criminal charges of "misbranding" in 2007, admitting that it was "well aware of the incorrect view held by many physicians that oxycodone was weaker than morphine" and "did not want to do anything 'to make physicians think that oxycodone was stronger or equal to morphine' or to 'take any steps ... that would affect the unique position that OxyContin'" held among physicians.

176. Even though oxycodone did not have the same stigma as morphine, in focus groups conducted before OxyContin's release, Purdue learned that doctors were concerned about the abuse potential of opioids. The focus group concluded that the perceived abuse potential of opioids was the "'biggest negative' that might prevent widespread use of the drug."

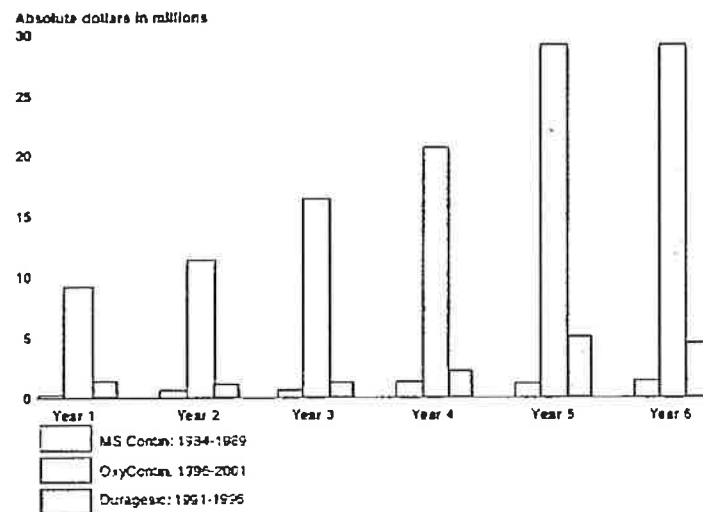
177. For Purdue and OxyContin to be "*really* big," Purdue needed to both distance its new product from the traditional view of narcotic addiction risk and broaden the drug's uses beyond cancer pain and hospice care. A marketing memo sent to Purdue's top sales executives in March 1995 recommended that if Purdue could show that the risk of abuse was lower with OxyContin than with traditional immediate-release narcotics, sales would increase. As described

below, Purdue did not have any such evidence, but this did not stop Purdue from making that claim regardless.

178. Armed with this and other misrepresentations about the risks and benefits of its new drug, Purdue was able to open an enormous untapped market: patients with non-end-of-life, non-acute, everyday aches, and pains. As Dr. David Haddox (“Dr. Haddox”), a Senior Medical Director at Purdue, declared, “[t]here are 50 million patients in this country who have chronic pain that’s not being managed appropriately every single day. OxyContin is one of the choices that doctors have available to them to treat that.”

179. In pursuit of those 50 million potential customers, Purdue poured resources into OxyContin’s sales force and advertising, particularly to a far broader audience of primary care physicians who treated patients with chronic pain complaints. The graph below shows how promotional spending in the first six years following OxyContin’s launch dwarfed Purdue’s spending on MS Contin or Defendant Janssen’s spending on its opioid product Duragesic.

Figure 1: Promotional Spending for Three Opioid Analgesics in First 5 Years of Sales



Source: DEA and BMS Health Integrated Promotional Service Audit

Note: Dollars are 2002 adjusted.

180. Prior to Purdue's launch of OxyContin, no drug company had ever promoted such a pure, high-strength Schedule II narcotic to so wide an audience of general practitioners.

181. In the two decades following OxyContin's launch, Purdue continued to devote substantial resources to its promotional efforts.

182. Purdue has generated estimated sales of more than \$35 billion from opioids since 1996, raking in more than \$3 billion in 2015 alone. Remarkably, its opioid sales continued to climb even after a period of media attention and government inquiries regarding OxyContin abuse in the early 2000s and a criminal investigation culminating in guilty pleas in 2007. Purdue proved itself skilled at evading full responsibility and continuing to sell through the controversy. The company's annual opioid sales of \$3 billion in 2015 represent a four-fold increase from its 2006 sales of \$800 million.

183. One might imagine that Richard Sackler's ambitions have been realized. But in the best tradition of family patriarch Arthur Sackler, Purdue has its eyes on even greater profits. Under the name of Mundipharma, the Sacklers are looking to new markets for their opioids—employing the exact same playbook in South America, China, and India as they did in the United States.

184. In May 2017, a dozen members of Congress sent a letter to the World Health Organization, warning it of the deceptive practices Purdue is unleashing on the rest of the world through Mundipharma:

We write to warn the international community of the deceptive and dangerous practices of Mundipharma International—an arm of Purdue Pharmaceuticals. The greed and recklessness of one company and its partners helped spark a public health crisis in the United States that will take generations to fully repair. We urge the World Health Organization (WHO) to do everything in its power to avoid allowing the same people to begin a worldwide opioid epidemic. Please learn from our experience and do not allow Mundipharma to carry on Purdue's deadly legacy on a global stage. . . .

Internal documents revealed in court proceedings now tell us that since the early development of OxyContin, Purdue was aware of the high risk of addiction it

carried. Combined with the misleading and aggressive marketing of the drug by its partner, Abbott Laboratories, Purdue began the opioid crisis that has devastated American communities since the end of the 1990s. Today, Mundipharma is using many of the same deceptive and reckless practices to sell OxyContin abroad. . . .

In response to the growing scrutiny and diminished U.S. sales, the Sacklers have simply moved on. On December 18, the Los Angeles Times published an extremely troubling report detailing how in spite of the scores of lawsuits against Purdue for its role in the U.S. opioid crisis, and tens of thousands of overdose deaths, Mundipharma now aggressively markets OxyContin internationally. In fact, Mundipharma uses many of the same tactics that caused the opioid epidemic to flourish in the U.S., though now in countries with far fewer resources to devote to the fallout.

185. Purdue's recent pivot to untapped markets—after extracting substantial profits from American communities and leaving local governments to address the devastating and still growing damage the company caused—only serves to underscore that Purdue's actions have been knowing, intentional, and motivated by profits throughout this entire story.

C. Other Manufacturer Defendants Leapt at the Opioid Opportunity

186. Purdue created a market for the use of opioids for a range of common aches and pains by misrepresenting the risks and benefits of its opioids, but it was not alone. The other Manufacturer Defendants—already manufacturers of prescription opioids—positioned themselves to take advantage of the opportunity Purdue created, developing both branded and generic opioids to compete with OxyContin, while, together with Purdue and each other, misrepresenting the safety and efficacy of their products. These misrepresentations are described in detail in Section D below.

187. Endo, which already sold Percocet and Percodan, was the first to submit an application for generic extended-release oxycodone to compete with OxyContin. At the same time, Endo sought FDA approval for another potent opioid, immediate-release and extended-release oxymorphone, branded as Opana and Opana ER. Oxymorphone, like OxyContin's active ingredient oxycodone, is not a new drug; it was first synthesized in Germany in 1914 and sold in

the U.S. by Endo beginning in 1959 under the trade name Numorphan. But Numorphan tablets proved highly susceptible to abuse. Called “blues” after the light blue color of the 10 mg pills, Numorphan provoked, according to some users, a more euphoric high than heroin. As the National Institute on Drug Abuse observed in its 1974 report, “Drugs and Addict Lifestyle,” Numorphan was extremely popular among addicts for its quick and sustained effect. Endo withdrew oral Numorphan from the market in 1979.

188. Two decades later, however, as communities around the U.S. were first sounding the alarm about prescription opioids and Purdue executives were being called to testify before Congress about the risks of OxyContin, Endo essentially reached back into its inventory, dusted off a product it had previously shelved after widespread abuse, and reintroduced it into the marketplace with a new trade name, Opana.

189. The clinical trials submitted with Endo’s first application for approval of Opana were insufficient to demonstrate efficacy, and some subjects in the trials overdosed and had to be revived with naloxone. Endo then submitted new “enriched enrollment” clinical trials - in which trial subjects who do not respond to the drug are excluded from the trial - and obtained approval. Endo began marketing Opana and Opana ER, an extended-release formulation, in 2006.

190. Like Numorphan, Opana ER was highly susceptible to abuse. On June 8, 2017, the FDA sought removal of Opana ER. In its press release, the FDA indicated that this is the first time the agency has taken steps to remove a currently marketed opioid pain medication from sale due to the public health consequences of abuse. On July 6, 2017, Endo agreed to withdraw Opana ER from the market.

191. Janssen, which already marketed the Duragesic (fentanyl) patch for severe pain, also joined Purdue in pursuit of the broader chronic pain market. It sought to expand the use of

Duragesic through, for example, advertisements proclaiming, “It’s not just for end-stage cancer anymore!” This claim earned Janssen a warning letter from the FDA, for representing that Duragesic was “more useful in a broader range of conditions or patients than has been demonstrated by substantial evidence.”

192. Janssen also developed a new opioid compound called tapentadol in 2009, marketed as Nucynta for the treatment of moderate to severe pain. Janssen launched the extended-release version, Nucynta ER, for treatment of chronic pain in 2011.

193. By adding additional opioids or expanding the use of their existing opioid products, the other Manufacturer Defendants took advantage of the market created by Purdue’s aggressive promotion of OxyContin and reaped enormous profits. For example, Opana ER alone generated more than \$1 billion in revenue for Endo in 2010 and again in 2013. Janssen also passed the \$1 billion mark in sales of Duragesic in 2009.

III. DEFENDANTS’ CONDUCT CREATED AN ABATABLE PUBLIC NUISANCE

194. Defendants’ conduct created a public health crisis and a public nuisance.

195. The public nuisance—i.e., the opioid epidemic—created, perpetuated, and maintained by Defendants can be abated and further recurrence of such harm and inconvenience can be abated by, *inter alia*, (a) educating prescribers (especially primary care physicians and the most prolific prescribers of opioids) and patients regarding the true risks and benefits of opioids, including the risk of addiction, in order to prevent the next cycle of addiction; (b) providing addiction treatment to patients who are already addicted to opioids, and (c) making naloxone widely available so that overdoses are less frequently fatal.

196. Defendants have the ability to act to abate the public nuisance, and the law recognizes that they are uniquely well-positioned to do so. The manufacturer of a drug has a duty to assure the safety and efficacy of the drug and the appropriateness of the drug’s labeling,

marketing, and promotion. All companies in the supply chain of a controlled substance have a duty to ensure that such drugs are only distributed and dispensed to appropriate patients and not diverted. These duties exist independently of any federal or state statute or regulation. As registered manufacturers and distributors of controlled substances, Defendants occupy a position of special trust and responsibility and are uniquely positioned, based on their knowledge of prescribers and orders, to act as the first line of defense against the harm that opioids can cause.

IV. THE MANUFACTURER DEFENDANTS' MULTI-PRONGED SCHEME TO CHANGE PRESCRIBER HABITS AND PUBLIC PERCEPTION AND INCREASE DEMAND FOR OPIOIDS

197. In order to accomplish the fundamental shift in perception that was key to successfully marketing their opioids, the Manufacturer Defendants designed and implemented a sophisticated and deceptive marketing strategy. Lacking legitimate scientific research to support their claims, the Manufacturer Defendants turned to the marketing techniques first pioneered by Arthur Sackler to create a series of misperceptions in the medical community and ultimately reverse the long-settled understanding of the relative risks and benefits of opioids.

198. The Manufacturer Defendants promoted and profited from, their misrepresentations about the risks and benefits of opioids for chronic pain even though they knew that their marketing was false and misleading. The history of opioids, as well as research and clinical experience over the last 20 years, established that opioids were highly addictive and responsible for a long list of very serious adverse outcomes. The FDA and other regulators warned Manufacturer Defendants of these risks. The Manufacturer Defendants had access to scientific studies, detailed prescription data, and reports of adverse events, including reports of addiction, hospitalization, and deaths—all of which made clear the harms from long-term opioid use and that patients are suffering from addiction, overdoses, and death in alarming numbers. More recently,

the FDA and CDC issued pronouncements based on existing medical evidence that conclusively expose the known falsity of these Defendants' misrepresentations.

199. The marketing scheme to increase opioid prescriptions centered around nine categories of misrepresentations, which are discussed in detail below. The Manufacturer Defendants disseminated these misrepresentations through various channels, including through advertising, sales representatives, purportedly independent organizations these defendants funded and controlled ("Front Groups"), KOLs, and CME programs discussed below.

A. The Manufacturer Defendants Promoted Multiple Falsehoods about Opioids

200. The Manufacturer Defendants' misrepresentations fall into the following nine categories:

- a. The risk of addiction from chronic opioid therapy is low
- b. To the extent there is a risk of addiction, it can be easily identified and managed
- c. Signs of addictive behavior are "pseudoaddiction," requiring more opioids
- d. Opioid withdrawal can be avoided by tapering
- e. Opioid doses can be increased without limit or greater risks
- f. Long-term opioid use improves functioning
- g. Alternative forms of pain relief pose greater risks than opioids
- h. OxyContin provides twelve hours of pain relief
- i. New formulations of certain opioids successfully deter abuse

201. Each of these propositions was false. The Manufacturer Defendants knew this, but they nonetheless set out to convince physicians, patients, and the public at large of the truth of each of these propositions in order to expand the market for their opioids.

202. The foregoing categories of misrepresentations are offered to organize the numerous statements the Manufacturer Defendants made and to explain their role in the overall

marketing effort, not as a checklist for assessing each Manufacturer Defendant's liability. While each Manufacturer Defendant deceptively promoted their opioids specifically, and, together with other Manufacturer Defendants, opioids generally, not every Manufacturer Defendant propagated (or needed to propagate) each misrepresentation. Each Manufacturer Defendant's conduct, and each misrepresentation, contributed to an overall narrative that aimed to—and did—mislead doctors, patients, and payors about the risks and benefits of opioids. While this Complaint endeavors to document examples of each Manufacturer Defendant's misrepresentations and the manner in which they were disseminated, they are just that—examples. The Complaint is not, especially prior to discovery, an exhaustive catalog of the nature and manner of each deceptive statement by each Manufacturer Defendant.

1. Falsehood #1: The risk of addiction from chronic opioid therapy is low

203. Central to the Manufacturer Defendants' promotional scheme was the misrepresentation that opioids are rarely addictive when taken for chronic pain. Through their marketing efforts, the Manufacturer Defendants advanced the idea that the risk of addiction is low when opioids are taken as prescribed by "legitimate" pain patients. That, in turn, directly led to the expected and intended result that doctors prescribed more opioids to more patients—thereby enriching the Manufacturer Defendants and substantially contributing to the opioid epidemic.

204. Each of the Manufacturer Defendants claimed that the potential for addiction from its opioids was relatively small or non-existent, even though there was no scientific evidence to support those claims. None of them have acknowledged, retracted, or corrected their false statements.

205. In fact, studies have shown that a substantial percentage of long-term users of opioids experience addiction. Addiction can result from the use of any opioid, "even at the

recommended dose,” and the risk substantially increases with more than three months of use. As the CDC Guideline states, “[o]pioid pain medication use presents serious risks, including overdose and opioid use disorder” (a diagnostic term for addiction).

a. Purdue’s misrepresentations regarding addiction risk

206. When it launched OxyContin, Purdue knew it would need data to overcome decades of wariness regarding opioid use. It needed some sort of research to back up its messaging. But Purdue had not conducted any studies about abuse potential or addiction risk as part of its application for FDA approval for OxyContin. Purdue (and, later, the other Defendants) found this “research” in the form of a one-paragraph letter to the editor published in the *New England Journal of Medicine* (NEJM) in 1980.

207. This letter, by Dr. Hershel Jick and Jane Porter, declared the incidence of addiction “rare” for patients treated with opioids. They had analyzed a database of hospitalized patients who were given opioids in a controlled setting to ease suffering from acute pain. Porter and Jick considered a patient not addicted if there was no sign of addiction noted in patients’ records.

ADDICTION RARE IN PATIENTS TREATED
WITH NARCOTICS

To the Editor: Recently, we examined our current files to determine the incidence of narcotic addiction in 39,946 hospitalized medical patients¹ who were monitored consecutively. Although there were 11,882 patients who received at least one narcotic preparation, there were only four cases of reasonably well documented addiction in patients who had no history of addiction. The addiction was considered major in only one instance. The drugs implicated were meperidine in two patients,² Percodan in one, and hydromorphone in one. We conclude that despite widespread use of narcotic drugs in hospitals, the development of addiction is rare in medical patients with no history of addiction.

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1. Jick H, Miettinen OS, Shapiro S, Lewis GP, Siskind Y, Slone D. Comprehensive drug surveillance. JAMA. 1970; 213:1455-60.
2. Miller RR, Jick H. Clinical effects of meperidine in hospitalized medical patients. J Clin Pharmacol. 1972; 18:180-8.

208. As Dr. Jick explained to a journalist years later, he submitted the statistics to NEJM as a letter because the data were not robust enough to be published as a study.

209. Purdue nonetheless began repeatedly citing this letter in promotional and educational materials as evidence of the low risk of addiction, while failing to disclose that its source was a letter to the editor, not a peer-reviewed paper. Citation of the letter, which was largely ignored for more than a decade, significantly increased after the introduction of OxyContin. While first Purdue and then other Manufacturer Defendants used it to assert that their opioids were not addictive, “that’s not in any shape or form what we suggested in our letter,” according to Dr. Jick.

210. Purdue specifically used the Porter and Jick letter in its 1998 promotional video “I got my life back,” in which Dr. Alan Spanos says, “In fact, the rate of addiction amongst pain patients who are treated by doctors *is much less than 1%*.” Purdue trained its sales representatives to tell prescribers that fewer than 1% of patients who took OxyContin became addicted. In 1999, a Purdue-funded study of patients who used OxyContin for headaches found that the addiction rate was thirteen percent, but that finding was not included by Purdue in any of its advertising, marketing, or promotional or sales material; nor was it otherwise provided by Purdue to physicians.

211. Other Defendants relied on and disseminated the same distorted messaging. The enormous impact of Defendants’ misleading amplification of this letter was well documented in another letter published in the NEJM on June 1, 2017, describing the way the one-paragraph 1980 letter had been irresponsibly cited and, in some cases, “grossly misrepresented.” In particular, the authors of this letter explained:

[W]e found that a five-sentence letter published in the *Journal* in 1980 was heavily and uncritically cited as evidence that addiction was rare with long-term opioid therapy. We believe that this citation pattern contributed to the North American opioid crisis by helping to shape a narrative that allayed prescribers’ concerns about the risk of addiction associated with long-term opioid therapy . . .

212. “It’s difficult to overstate the role of this letter,” said Dr. David Juurlink of the University of Toronto, who led the analysis. “It was the key bit of literature that helped the opiate manufacturers convince front-line doctors that addiction is not a concern.”

213. Alongside its use of the Porter and Jick letter, Purdue also crafted its own materials and spread its deceptive message through numerous additional channels. In its 1996 press release announcing the release of OxyContin, for example, Purdue declared, “The fear of addiction is exaggerated.”

214. At a hearing before the House of Representatives’ Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce in August 2001, Purdue emphasized “legitimate” treatment, dismissing cases of overdose and death as something that would not befall “legitimate” patients: “Virtually all of these reports involve people who are abusing the medication, not patients with legitimate medical needs under the treatment of a healthcare professional.”

215. Purdue spun this baseless “legitimate use” distinction out even further in a patient brochure about OxyContin, called “A Guide to Your New Pain Medicine and How to Become a Partner Against Pain.” In response to the question “Aren’t opioid pain medications like OxyContin Tablets ‘addicting’?” Purdue claimed that there was no need to worry about addiction if taking opioids for legitimate, “medical” purposes:

Drug addiction means using a drug to get “high” rather than to relieve pain. You are taking opioid pain medication for medical purposes. The medical purposes are clear and the effects are beneficial, not harmful.

216. Sales representatives marketed OxyContin as a product “to start with and to stay with.” Sales representatives also received training in overcoming doctors’ concerns about addiction with talking points they knew to be untrue about the drug’s abuse potential. One of Purdue’s early training memos compared doctor visits to “firing at a target,” declaring that “[a]s

you prepare to fire your ‘message,’ you need to know where to aim and what you want to hit!” According to the memo, the target is physician resistance based on concern about addiction: “The physician wants pain relief for these patients without addicting them to an opioid.”

217. Through its unbranded website, *Partners Against Pain*, Purdue stated the following: “Current Myth: Opioid addiction (psychological dependence) is an important clinical problem in patients with moderate to severe pain treated with opioids. Fact: Fears about psychological dependence are exaggerated when treating appropriate pain patients with opioids.” “Addiction risk also appears to be low when opioids are dosed properly for chronic, noncancer pain.”

218. Former sales representative Steven May, who worked for Purdue from 1999 to 2005, explained to a journalist how he and his coworkers were trained to overcome doctors’ objections to prescribing opioids. The most common objection he heard about prescribing OxyContin was that “it’s just too addictive.” May and his coworkers were trained to “refocus” doctors on “legitimate” pain patients and to represent that “legitimate” patients would not become addicted. In addition, they were trained to say that the 12-hour dosing made the extended-release opioids less “habit-forming” than painkillers than need to be taken every four hours.

219. According to interviews with prescribers and former Purdue sales representatives, Purdue has continued to distort or omit the risk of addiction while failing to correct its earlier misrepresentations, leaving many doctors with the false impression that pain patients will only rarely become addicted to opioids.

220. With regard to addiction, Purdue’s label for OxyContin has not sufficiently disclosed the true risks to, and experience of, its patients. Until 2014, the OxyContin label stated

in a black-box warning that opioids have “abuse potential” and that the “risk of abuse is increased in patients with a personal or family history of substance abuse.”

221. However, the FDA made clear to Purdue as early as 2001 that the disclosures in its OxyContin label were insufficient.

222. In 2001, Purdue revised the indication and warnings for OxyContin. In the United States, Purdue ceased distributing the 160 mg tablet of OxyContin.

223. In the end, Purdue narrowed the recommended use of OxyContin to situations when “a continuous, around-the-clock analgesic is needed for an extended period of time” and added a warning that “[t]aking broken, chewed, or crushed OxyContin tablets” could lead to a “potentially fatal dose.” However, Purdue did not, until 2014, change the label to indicate that OxyContin should not be the first therapy, or even the first opioid, used, and did not disclose the incidence or risk of overdose and death even when OxyContin was not abused. Purdue announced the label changes in a letter to health care providers.

224. Purdue was aware that there was a perception that oxycodone is safer than morphine but did not attempt to correct that misunderstanding and instead exploited it.

b. Endo’s misrepresentations regarding addiction risk

225. Endo also falsely represented that addiction is rare in patients who are prescribed opioids.

226. Until April 2012, Endo’s website for Opana, www.opana.com, stated that “[m]ost healthcare providers who treat patients with pain agree that patients treated with prolonged opioid medicines usually do not become addicted.”

227. Endo improperly instructed its sales representatives to diminish and distort the risk of addiction associated with Opana ER. Endo’s training materials for its sales representatives in

2011 also prompted sales representatives to answer “true” to the statement that addiction to opioids is not common.

228. One of the Front Groups with which Endo worked most closely was the American Pain Foundation (“APF”), described more fully below. Endo provided substantial assistance to, and exercised editorial control, over the deceptive and misleading messages that APF conveyed through its National Initiative on Pain Control (“NIPC”) and its website *Painknowledge.com*, which claimed that “[p]eople who take opioids as prescribed usually do not become addicted.”

229. Endo was one of the APF’s biggest financial supporters, providing more than half of the \$10 million APF received from opioid manufacturers during its lifespan. Endo was the sole funder of NIPC and selected APF to manage NIPC. Endo was responsible for NIPC curriculum development, web posting, and workshops developed and reviewed NIPC content, and took a substantial role in distributing NIPC and APF materials. Endo projected that it would be able to reach tens of thousands of prescribers nationwide through the distribution of NIPC materials.

230. Another Endo website, *PainAction.com*, stated: “Did you know? Most chronic pain patients do not become addicted to the opioid medications that are prescribed for them.”

231. A brochure available on *Painknowledge.com* titled “*Pain: Opioid Facts*,” Endo-sponsored NIPC stated that “people who have no history of drug abuse, including tobacco, and use their opioid medication as directed will probably not become addicted.” In numerous patient education pamphlets, Endo repeated this deceptive message.

232. In a patient education pamphlet titled “*Understanding Your Pain: Taking Oral Opioid Analgesics*,” Endo answers the hypothetical patient question of “What should I know about opioids and addiction?” by focusing on explaining what addiction is (“a chronic brain disease”) and what it is not (“taking opioids for pain relief”). It goes on to explain that “[a]ddicts take opioids

for other reasons, such as unbearable emotional problems. Taking opioids as prescribed for pain relief is not addiction.” This publication is still available online.

233. An Endo publication, *Living with Someone with Chronic Pain*, stated, “Most health care providers who treat people with pain agree that most people do not develop an addiction problem.” A similar statement appeared on the Endo website, www.opana.com, until at least April 2012.

234. In addition, a 2009 patient education publication, *Pain: Opioid Therapy*, funded by Endo and posted on Painknowledge.com, omitted addiction from the “common risks” of opioids, as shown below:

As with any medication, there are some side effects that are associated with opioid therapy. The most common side effects that occur with opioid use include the following:

- Constipation
- Drowsiness
- Confusion
- Nausea
- Itching
- Dizziness
- Shortness of breath

Your healthcare provider can help to address and, in some cases, prevent side effects that may occur as a result of opioid treatment. Less severe side effects, including nausea, itching, or drowsiness, typically go away within a few days without the need for further treatment. If you experience any side effects, you should let your healthcare provider know immediately.

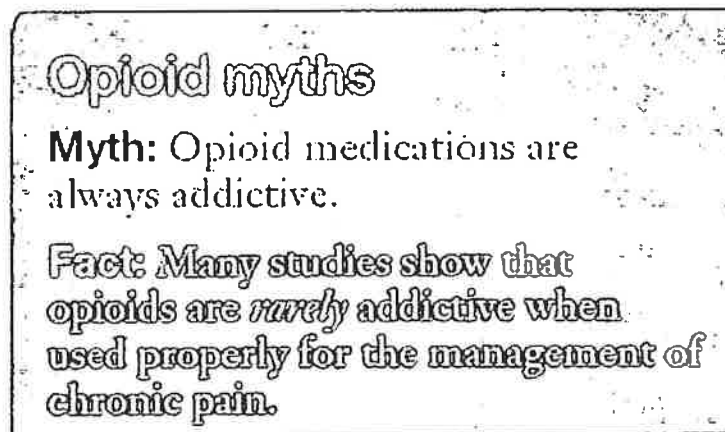
c. Janssen’s misrepresentations regarding addiction risk

235. Janssen likewise misrepresented the addiction risk of opioids. One website, *Let’s Talk Pain*, states, among other things, that “the stigma of drug addiction and abuse” associated with the use of opioids stemmed from a “lack of understanding about addiction.” The website carried Janssen’s trademark and was copy approved and controlled by Janssen.

236. The *Let’s Talk Pain* website also perpetuated the concept of pseudoaddiction, associating patient behaviors such as “drug-seeking,” “clock watching,” and “even illicit drug use or deception” with undertreated pain which can be resolved with “effective pain management.”

237. A Janssen unbranded website, *PrescribeResponsibly.com*, states that concerns about opioid addiction are “overestimated” and that “true addiction occurs only in a small percentage of patients.”

238. Janssen reviewed, edited, approved, and distributed a patient education guide entitled *Finding Relief: Pain Management for Older Adults*, which, as seen below, described as a “myth” the claim that opioids are addictive, and asserted as “fact” that “[m]any studies show that opioids are rarely addictive when used properly for the management of chronic pain.” Until recently, this guide was still available online.



239. Janssen’s website for Duragesic included a section addressing “Your Right to Pain Relief” and a hypothetical patient’s fear that “I’m afraid I’ll become a drug addict.” The website’s response: “Addiction is relatively rare when patients take opioids appropriately.”

d. Cephalon’s misrepresentations regarding addiction risk.

240. Cephalon sponsored and facilitated the development of a guidebook, *Opioid Medications, and REMS: A Patient’s Guide*, which included claims that “patients without a history of abuse or a family history of abuse do not commonly become addicted to opioids.” Similarly, Cephalon sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007),

which taught that addiction is rare and limited to extreme cases of unauthorized dose escalations, obtaining opioids from multiple sources, or theft.

241. For example, a 2003 Cephalon-sponsored CME presentation titled *Pharmacologic Management of Breakthrough or Incident Pain*, posted on Medscape in February 2003, teaches:

[C]hronic pain is often undertreated, particularly in the noncancer patient population The continued stigmatization of opioids and their prescription, coupled with often unfounded and self-imposed physician fear of dealing with the highly regulated distribution system for opioid analgesics, remains a barrier to effective pain management and must be addressed. Clinicians intimately involved with the treatment of patients with chronic pain recognize that the majority of suffering patients lack interest in substance abuse. In fact, patients' fears of developing substance abuse behaviors such as addiction often lead to undertreatment of pain. The concern about patients with chronic pain becoming addicted to opioids during long-term opioid therapy may stem from confusion between physical dependence (tolerance) and psychological dependence (addiction) that manifests as drug abuse.

e. Actavis's misrepresentations regarding addiction risk.

242. Through its "Learn More about customized pain control with Kadian," material, Actavis claimed that it is possible to become addicted to morphine-based drugs like Kadian, but that it is "less likely" to happen in those who "have never had an addiction problem." The piece goes on to advise that a need for a "dose adjustment" is the result of tolerance, and "not addiction."

243. Training for Actavis sales representatives deceptively minimizes the risk of addiction by (i) attributing addiction to "predisposing factors" like family history of addiction or psychiatric disorders; (ii) repeatedly emphasizing the difference between substance dependence and substance abuse; and (iii) using the term pseudoaddiction, which, as described below, dismisses evidence of addiction as the undertreatment of pain and, dangerously, counsels doctors to respond to its signs with more opioids.

244. Actavis conducted a market study on takeaways from prescribers' interactions with Kadian sales representatives. The doctors had a strong recollection of the sales representatives'

discussion of the low-abuse potential. Actavis' sales representatives' misstatements on the low-abuse potential were considered an important factor to doctors and were most likely repeated and reinforced to their patients. Additionally, doctors reviewed visual aids that the Kadian sales representatives use during the visits, and Actavis noted that doctors associate Kadian with less abuse and no highs, in comparison to other opioids. Numerous marketing surveys of doctors in 2010 and 2012, for example, confirmed Actavis's messaging about Kadian's purported low addiction potential, and that it had less abuse potential than other similar opioids.

245. A guide for prescribers under Actavis's copyright deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. The guide includes the following statements: (i) "unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users," and (ii) KADIAN may be less likely to be abused by health care providers and illicit users" because of "Slow onset of action," "Lower peak plasma morphine levels than equivalent doses of other formulations of morphine," "Long duration of action," and "Minimal fluctuations in peak to trough plasma levels of morphine at steady state." These statements falsely convey both that (i) Kadian does not cause euphoria and therefore is less addictive and that (ii) Kadian is less prone to tampering and abuse, even though Kadian was not approved by the FDA as abuse-deterrent, and Actavis had no studies to suggest it was.

f. Mallinckrodt's misrepresentations regarding addiction risk

246. As described below, Mallinckrodt promoted its branded opioids Exalgo and Xartemis XR, and opioids generally, in a campaign that consistently mischaracterized the risk of addiction. Mallinckrodt did so through its website and sales force, as well as through unbranded communications distributed through C.A.R.E.S. Alliance.

247. Mallinckrodt in 2010 created the C.A.R.E.S. Alliance (the initials stand for “Collaborating and Acting Responsibly to Ensure Safety”), which it describes as “a coalition of national patient safety, provider and drug diversion organizations that are focused on reducing opioid pain medication abuse and increasing responsible prescribing habits.” “C.A.R.E.S. Alliance” is a service mark of Mallinckrodt LLC (and was previously a service mark of Mallinckrodt, Inc.) copyrighted and registered as a trademark by Covidien, its former parent company. Materials distributed by the C.A.R.E.S. Alliance, however, include unbranded publications that do not disclose a link to Mallinckrodt.

248. By 2012, Mallinckrodt, through the C.A.R.E.S. Alliance, was promoting a book titled *Defeat Chronic Pain Now!* This book is still available online. The false claims and misrepresentations in this book include the following statements:

- a. “Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction.”
- b. “It is currently recommended that every chronic pain patient suffering from moderate to severe pain be viewed as a potential candidate for opioid therapy.”
- c. “When chronic pain patients take opioids to treat their pain, they rarely develop a true addiction and drug craving.”
- d. “Only a minority of chronic pain patients who are taking long-term opioids develop tolerance.”
- e. “**The bottom line:** Only rarely does opioid medication cause a true addiction when prescribed appropriately to a chronic pain patient who does not have a prior history of addiction.”

f. “Here are the facts. It is very uncommon for a person with chronic pain to become ‘addicted’ to narcotics IF (1) he doesn’t have a prior history of any addiction and (2) he only takes the medication to treat pain.”

g. “Studies have shown that many chronic pain patients can experience significant pain relief with tolerable side effects from opioid narcotic medication when taken daily and no addiction.”

249. In a 2013 *Mallinckrodt Pharmaceuticals Policy Statement Regarding the Treatment of Pain and Control of Opioid Abuse*, which is still available online, Mallinckrodt stated that “[s]adly, even today, pain frequently remains undiagnosed and either untreated or undertreated” and cites to a report that concludes that “the majority of people with pain use their prescription drugs properly, are not a source of misuse, and should not be stigmatized or denied access because of the misdeeds or carelessness of others.”

250. Manufacturer Defendants’ suggestions that the opioid epidemic is the result of bad patients who manipulate doctors to obtain opioids illicitly helped further their marketing scheme but are at odds with the facts. While there are certainly patients who unlawfully obtain opioids, they are a small minority. For example, patients who “doctor-shop”—i.e., visit multiple prescribers to obtain opioid prescriptions—are responsible for roughly 2% of opioid prescriptions. The epidemic of opioid addiction and abuse is overwhelmingly a problem of false marketing and irresponsible distribution of the drugs.

2. *Falsehood #2: To the extent, there is a risk of addiction, it can be easily identified and managed*

251. While continuing to maintain that most patients can safely take opioids long-term for chronic pain without becoming addicted, the Manufacturer Defendants asserted that to the extent that *some* patients are at risk of opioid addiction, doctors can effectively identify and manage

that risk by using screening tools or questionnaires. In materials they produced, sponsored, or controlled, Defendants instructed patients and prescribers that screening tools can identify patients predisposed to addiction, thus making doctors feel more comfortable prescribing opioids to their patients and patients more comfortable starting opioid therapy for chronic pain. These tools, they say, identify those with higher addiction risks (stemming from personal or family histories of substance use, mental illness, trauma, or abuse) so that doctors can then more closely monitor those patients.

252. Purdue provided to prescribers its *Partners Against Pain* “Pain Management Kit,” which contains several screening tools, and catalogs of Purdue materials, which included these tools. Janssen, on its website PrescribeResponsibly.com, states that the risk of opioid addiction “can usually be managed” through tools such as opioid agreements between patients and doctors. The website, which directly provides screening tools to prescribers for risk assessments, includes a “[f]our question screener” to purportedly help physicians identify and address possible opioid misuse.

253. Purdue and Cephalon sponsored the APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which also falsely reassured patients that opioid agreements between doctors and patients can “ensure that you take the opioid as prescribed.”

254. Purdue sponsored a 2011 webinar taught by Dr. Lynn Webster, a KOL discussed below, entitled *Managing Patient’s Opioid Use: Balancing the Need and Risk*. This publication misleadingly taught prescribers that screening tools, urine tests, and patient agreements have the effect of preventing “overuse of prescriptions” and “overdose deaths.”

255. Purdue sponsored a 2011 CME program titled *Managing Patient’s Opioid Use: Balancing the Need and Risk*. This presentation deceptively instructed prescribers that screening

tools, patient agreements, and urine tests prevented “overuse of prescriptions” and “overdose deaths.”

256. Purdue also funded a 2012 CME program called *Chronic Pain Management and Opioid Use: Easing Fears, Managing Risks, and Improving Outcomes*. The presentation deceptively instructed prescribers that, through the use of screening tools, more frequent refills, and other techniques, even high-risk patients showing signs of addiction could be treated with opioids.

257. Endo paid for a 2007 supplement available for continuing education credit in the *Journal of Family Practice* written by a doctor who became a member of Endo’s speaker’s bureau in 2010. This publication, entitled *Pain Management Dilemmas in Primary Care: Use of Opioids*, (i) recommended screening patients using tools like (a) the *Opioid Risk Tool* (“ORT”) created by Dr. Webster and linked to Janssen or (b) the *Screening and Opioid Assessment for Patients with Pain*, and (ii) taught that patients at high risk of addiction could safely receive chronic opioid therapy using a “maximally structured approach” involving toxicology screens and pill counts. The ORT was linked to by Endo-supported websites.

258. There are three fundamental flaws in the Manufacturer Defendants’ representations that doctors can consistently identify and manage the risk of addiction. First, there is no reliable scientific evidence that doctors can depend on the screening tools currently available to materially limit the risk of addiction. Second, there is no reliable scientific evidence that high-risk patients identified through screening can take opioids long-term without triggering addiction, even with enhanced monitoring. Third, there is no reliable scientific evidence that patients who are not identified through such screening can take opioids long-term without significant danger of addiction.

3. Falsehood #3: Signs of addictive behavior are “pseudoaddiction,” requiring more opioids

259. The Manufacturer Defendants instructed patients and prescribers that signs of addiction are actually indications of untreated pain, such that the appropriate response is to prescribe even more opioids. In 1989, Dr. Haddox, who later became a Senior Medical Director for Purdue, coined the term “pseudoaddiction,” which he described as “the iatrogenic syndrome of abnormal behavior developing as a direct consequence of inadequate pain management.” In plain English, the notion underlying “pseudoaddiction” is that people on prescription opioids who exhibit classic signs of addiction—for example, asking for more and higher doses of opioids, self-escalating their doses, or claiming to have lost prescriptions in order to get more opioids—are not “addicted,” but rather are simply suffering from undertreatment of their pain, which calls for more opioids.

260. In the materials and outreach they produced, sponsored, or controlled, Defendants made each of these misrepresentations and omissions, and have never acknowledged, retracted, or corrected them.

261. Cephalon, Endo, and Purdue sponsored the Federation of State Medical Boards’ (“FSMB”) *Responsible Opioid Prescribing* (2007) written by Dr. Scott Fishman (“Dr. Fishman”), a KOL discussed below, which taught that behaviors such as “requesting drugs by name,” “demanding or manipulative behavior,” seeing more than one doctor to obtain opioids, and hoarding, which are signs of genuine addiction, are all really signs of “pseudoaddiction.”

262. Purdue posted an unbranded pamphlet entitled *Clinical Issues in Opioid Prescribing* on its website, *PartnersAgainstPain.com*, in 2005, and circulated this pamphlet through at least 2007 and on its website through at least 2013. The pamphlet listed conduct

including “illicit drug use and deception” that it claimed was not evidence of true addiction but “pseudoaddiction” caused by untreated pain.

263. Purdue sales representatives were trained and tested on the meaning of pseudoaddiction, which they in turn communicated to prescribers.

264. Purdue’s Pain Management Kit endorses the concept of pseudoaddiction by claiming that “pain-relief seeking behavior can be mistaken for drug-seeking behavior.” The kit was in use from roughly 2011 through at least June 2016.

265. Similarly, Endo trained its sales representatives to promote the concept of pseudoaddiction. A training module taught sales representatives that addiction and pseudoaddiction were commonly confused. The module went on to state that: “The physician can differentiate addiction from pseudoaddiction by speaking to the patient about his/her pain and increasing the patient’s opioid dose to increase pain relief.”

266. Endo also sponsored a NIPC CME program in 2009 titled *Chronic Opioid Therapy: Understanding Risk While Maximizing Analgesia*, which promoted pseudoaddiction and listed “[d]ifferentiation among states of physical dependence, tolerance, pseudoaddiction, and addiction” as an element to be considered in awarding grants to CME providers.

267. The pseudoaddiction concept has never been empirically validated and in fact, has been abandoned by some of its proponents. The New York Attorney General, in a 2016 settlement with Endo, reported that “Endo’s Vice President for Pharmacovigilance and Risk Management testified to [the NY AG] that he was not aware of any research validating the ‘pseudoaddiction’ concept” and acknowledged the difficulty in distinguishing “between addiction and ‘pseudoaddiction.’” Endo thereafter agreed not to “use the term ‘pseudoaddiction’ in any training or marketing” in New York.

268. Janssen sponsored, funded, and edited a website called *Let's Talk Pain*, which in 2009 stated “pseudoaddiction ... refers to patient behaviors that may occur when *pain is undertreated* Pseudoaddiction is different from true addiction because such behaviors can be resolved with effective pain management.” This website was accessible online until at least May 2012.

269. Janssen also currently runs a website, *Prescriberresponsibly.com*, which claims that concerns about opioid addiction are “overestimated,” and describes pseudoaddiction as “a syndrome that causes patients to seek additional medications due to inadequate pharmacotherapy being prescribed. Typically when the pain is treated appropriately the inappropriate behavior ceases.”

270. The CDC Guideline nowhere recommends attempting to provide more opioids to patients exhibiting symptoms of addiction. Dr. Webster admitted that pseudoaddiction “is already something we are debunking as a concept” and became “too much of an excuse to give patients more medication. It led us down a path that caused harm.”

4. *Falsehood #4: Opioid withdrawal can be avoided by tapering*

271. In an effort to downplay the risk and impact of addiction, the Manufacturer Defendants falsely claimed that, while patients become physically dependent on opioids, physical dependence is not the same as addiction and can be easily addressed, if and when pain relief is no longer desired, by gradually tapering patients’ dose to avoid the adverse effects of withdrawal. Defendants fail to disclose the extremely difficult and painful effects that patients can experience when they are removed from opioids—adverse effects that also make it less likely that patients will be able to stop using the drugs. Defendants also failed to disclose how difficult it is for patients to stop using opioids after they have used them for a prolonged period.

272. A non-credit educational program sponsored by Endo, *Persistent Pain in the Older Adult*, claimed that withdrawal symptoms, which make it difficult for patients to stop using opioids, could be avoided by simply tapering a patient's opioid dose over ten days. However, this claim is at odds with the experience of patients addicted to opioids. Most patients who have been taking opioids regularly will, upon stopping treatment, experience withdrawal, characterized by intense physical and psychological effects, including anxiety, nausea, headaches, and delirium, among others. The painful and arduous struggle to terminate use can leave many patients unwilling or unable to give up opioids and heightens the risk of addiction.

273. Purdue sponsored the American Pain Foundation's ("APF") *A Policymaker's Guide to Understanding Pain & Its Management*, which taught that "Symptoms of physical dependence can often be ameliorated by gradually decreasing the dose of medication during discontinuation," but the guide did not disclose the significant hardships that often accompany cessation of use.

274. To this day, the Manufacturer Defendants have not corrected or retracted their misrepresentations regarding tapering as a solution to opioid withdrawal.

5. *Falsehood #5: Opioid doses can be increased without limit or greater risks*

275. In materials they produced, sponsored or controlled, Manufacturer Defendants instructed prescribers that they could safely increase patients' dose to achieve pain relief. Each of the Manufacturer Defendants' claims was deceptive in that it omitted warnings of increased adverse effects that occur at higher doses, effects confirmed by scientific evidence.

276. These misrepresentations were integral to the Manufacturer Defendants' promotion of prescription opioids. As discussed above, patients develop a tolerance to opioids' analgesic effects, so that achieving long-term pain relief requires constantly increasing the dose.

277. In a 1996 sales memo regarding OxyContin, for example, a regional manager for Purdue instructed sales representatives to inform physicians that there is “no[] upward limit” for dosing and ask “if there are any reservations in using a dose of 240mg-320mg of OxyContin.”

278. Purdue sales representatives aggressively pushed doctors to prescribe stronger doses of opioids. For example, one Purdue sales representative wrote about how his regional manager would drill the sales team on their upselling tactics:

It went something like this. “Doctor, what is the highest dose of OxyContin you have ever prescribed?” “20mg Q12h.” “Doctor, if the patient tells you their pain score is still high you can increase the dose 100% to 40mg Q12h, will you do that?” “Okay.” “Doctor, what if that patient then came back and said their pain score was still high, did you know that you could increase the OxyContin dose to 80mg Q12h, would you do that?” “I don’t know, maybe.” “Doctor, but you do agree that you would at least Rx the 40mg dose, right?” “Yes.”

The next week the rep would see that same doctor and go through the same discussion with the goal of selling higher and higher doses of OxyContin.

279. These misrepresentations were particularly dangerous. As noted above, opioid doses at or above 50 MME/day double the risk of overdose compared to 20 MME/day, and 50 MME is equal to just 33 mg of oxycodone. The recommendation of 320 mg every twelve hours is ten times that.

280. In its 2010 Risk Evaluation and Mitigation Strategy (“REMS”) for OxyContin, however, Purdue does not address the increased risk of respiratory depression and death from increasing dose, and instead advises prescribers that “dose adjustments may be made every 1-2 days”; “it is most appropriate to increase the q12h dose”; the “total daily dose can usually be increased by 25% to 50%”; and if “significant adverse reactions occur, treat them aggressively until they are under control, then resume upward titration.”

281. Endo sponsored a website, *Painknowledge.com*, which claimed that opioids may be increased until “you are on the right dose of medication for your pain,” at which point further dose increases would not be required.

282. Endo also published on its website a patient education pamphlet entitled *Understanding Your Pain: Taking Oral Opioid Analgesics*. In Q&A format, it asked, “If I take the opioid now, will it work later when I really need it?” The response is, “The dose can be increased You won’t ‘run out’ of pain relief.”

283. Purdue and Cephalon sponsored APF’s *Treatment Options: A Guide for People Living with Pain* (2007), which taught patients that opioids have “no ceiling dose” and therefore are safer than NSAIDs.

284. Manufacturer Defendants were aware of the greater dangers high dose opioids posed. In 2013, the FDA acknowledged “that the available data do suggest a relationship between increasing opioid dose and risk of certain adverse events” and that studies “appear to credibly suggest a positive association between high-dose opioid use and the risk of overdose and/or overdose mortality.” A study of the Veterans Health Administration from 2004 to 2008 found the rate of overdose deaths is directly related to the maximum daily dose.

6. Falsehood #6: Long-term opioid use improves functioning

285. Despite the lack of evidence of improved function and the existence of evidence to the contrary, the Manufacturer Defendants consistently promoted opioids as capable of improving patients’ function and quality of life because they viewed those claims as a critical part of their marketing strategies. In recalibrating the risk-benefit analysis for opioids, increasing the perceived benefits of treatment was necessary to overcome its risks.

286. Janssen, for example, promoted Duragesic as improving patients’ functioning and work productivity through an ad campaign that included the following statements: “[w]ork,

uninterrupted,” “[l]ife, uninterrupted,” “[g]ame, uninterrupted,” “[c]hronic pain relief that supports functionality,” and “[i]mprove[s] ... physical and social functioning.”

287. Purdue noted the need to compete with this messaging, despite the lack of data supporting improvement in the quality of life with OxyContin treatment:

Janssen has been stressing decreased side effects, especially constipation, as well as patient quality of life, as supported by patient rating compared to sustained-release morphine... We do not have such data to support OxyContin promotion. ... In addition, Janssen has been using the “life uninterrupted” message in the promotion of Duragesic for non-cancer pain, stressing that Duragesic “helps patients think less about their pain.” This is a competitive advantage based on our inability to make any quality of life claims.

288. Despite its acknowledgment that “[w]e do not have such data to support OxyContin promotion,” Purdue ran a full-page ad for OxyContin in the Journal of the American Medical Association, proclaiming, “There Can Be Life With Relief,” and showing a man happily fly-fishing alongside his grandson, implying that OxyContin would help users’ function. This ad earned a warning letter from the FDA, which admonished, “It is particularly disturbing that your November ad would tout ‘Life With Relief’ yet fail to warn that patients can die from taking OxyContin.”

289. Purdue sponsored APF’s *A Policymaker’s Guide to Understanding Pain & Its Management*, which claimed that “multiple clinical studies” have shown that opioids are effective in improving daily function, psychological health, and health-related quality of life for chronic pain patients. But the article cited as support for this, in fact, stated the contrary, noting the absence of long-term studies and concluding, “[f]or functional outcomes, the other analgesics were significantly more effective than were opioids.”

290. A series of medical journal advertisements for OxyContin in 2012 presented “Pain Vignettes”—case studies featuring patients with pain conditions persisting over several months—

that implied functional improvement. For example, one advertisement described a “writer with osteoarthritis of the hands” and implied that OxyContin would help him work more effectively.

291. Similarly, since at least May of 2011, Endo has distributed and made available on its website, *opana.com*, a pamphlet promoting Opana ER with photographs depicting patients with physically demanding jobs like those of a construction worker or chef, misleadingly implying that the drug would provide long-term pain relief and functional improvement.

292. As noted above, Janssen sponsored and edited a patient education guide entitled *Finding Relief: Pain Management for Older Adults* (2009), which states as “a fact” that “opioids may make it easier for people to live normally.” This guide features a man playing golf on the cover and lists examples of expected functional improvement from opioids, like sleeping through the night, returning to work, recreation, sex, walking, and climbing stairs. It assures patients that, “[u]sed properly, opioid medications can make it possible for people with chronic pain to ‘return to normal.’” Similarly, *Responsible Opioid Prescribing* (2007), sponsored and distributed by Teva, Endo, and Purdue, taught that relief of pain by opioids, by itself, improved patients’ function. The book remains for sale online.

293. In addition, Janssen’s *Let’s Talk Pain* website featured a video interview, which was edited by Janssen personnel, claiming that opioids were what allowed a patient to “continue to function,” falsely implying that her experience would be representative.

294. The APF’s *Treatment Options: A Guide for People Living with Pain* (2007), sponsored by Purdue and Cephalon, counseled patients that opioids “give [pain patients] a quality of life we deserve.” The guide was available online until APF shut its doors in May 2012.

295. Endo’s NIPC website *Painknowledge.com* claimed that with opioids, “your level of function should improve; you may find you are now able to participate in activities of daily

living, such as work and hobbies, that you were not able to enjoy when your pain was worse.” In addition to “improved function,” the website touted improved quality of life as a benefit of opioid therapy. The grant request that Endo approved for this project specifically indicated NIPC’s intent to make claims of functional improvement.

296. Endo was the sponsor, through NIPC, of a series of CMEs titled *Persistent Pain in the Older Patient*, which claimed that chronic opioid therapy has been “shown to reduce pain and improve depressive symptoms and cognitive functioning.” The CME was disseminated via webcast.

297. Mallinckrodt’s website, in a section on the responsible use of opioids, claims that “[t]he effective pain management offered by our medicines helps enable patients to stay in the workplace, enjoy interactions with family and friends, and remain an active member of society.”

298. The Manufacturer Defendants’ claims that long-term use of opioids improves patient function and quality of life are unsupported by clinical evidence. There are no controlled studies of the use of opioids beyond 16 weeks, and there is no evidence that opioids improve patients’ pain and function long term. The FDA, for years, has made clear through warning letters to manufacturers the lack of evidence for claims that the use of opioids for chronic pain improves patients’ function and quality of life. Based upon a review of the existing scientific evidence, the CDC Guideline concluded that “there is no good evidence that opioids improve pain or function with long-term use.”

299. Consistent with the CDC’s findings, substantial evidence exists demonstrating that opioid drugs are ineffective for the treatment of chronic pain and worsen patients’ health. For example, a 2006 study-of-studies found that opioids as a class did not demonstrate improvement in functional outcomes over other non-addicting treatments. The few longer-term studies of opioid

use had “consistently poor results,” and “several studies have shown that opioids for chronic pain may actually worsen pain and functioning ...” along with general health, mental health, and social function. Over time, even high doses of potent opioids often fail to control pain, and patients exposed to such doses are unable to function normally.

300. The available evidence indicates opioids may worsen patients’ health and pain. Increased duration of opioid use is strongly associated with increased prevalence of mental health disorders (depression, anxiety, post-traumatic stress disorder, and substance abuse), increased psychological distress, and greater health care utilization. The CDC Guideline concluded that “[w]hile benefits for pain relief, function and quality of life with long-term opioid use for chronic pain are uncertain, risks associated with long-term opioid use are clearer and significant.” According to the CDC, “for the vast majority of patients, the known, serious, and too-often fatal risks far outweigh the unproven and transient benefits [of opioids for chronic pain].”

301. As one pain specialist observed, “opioids may work acceptably well for a while, but over the long term, function generally declines, as does general health, mental health, and social functioning. Over time, even high doses of potent opioids often fail to control pain, and these patients are unable to function normally.” In fact, research such as a 2008 study in the journal *Spine* has shown that pain sufferers prescribed opioids long-term suffered addiction that made them more likely to be disabled and unable to work. Another study demonstrated that injured workers who received a prescription opioid for more than seven days during the first six weeks after the injury were 2.2 times more likely to remain on work disability a year later than workers with similar injuries who received no opioids at all. Moreover, the first randomized clinical trial designed to make head-to-head comparisons between opioids and other kinds of pain medications was published on March 6, 2018, in the Journal of the American Medical Association. The study

reported that “[t]here was no significant difference in pain-related function between the 2 groups”—those whose pain was treated with opioids and those whose pain was treated with non-opioids, including acetaminophen and other non-steroidal anti-inflammatory drugs (“NSAIDs”) like ibuprofen. Accordingly, the study concluded: “Treatment with opioids was not superior to treatment with nonopioid medications for improving pain-related function over 12 months.”

7. *Falsehood #7: Alternative forms of pain relief pose greater risks than opioids*

302. In materials they produced, sponsored or controlled, the Manufacturer Defendants omitted known risks of chronic opioid therapy and emphasized or exaggerated risks of competing for products so that prescribers and patients would favor opioids over other therapies such as over-the-counter acetaminophen or over-the-counter or prescription NSAIDs.

303. For example, in addition to failing to disclose in promotional materials the risks of addiction, overdose, and death, the Manufacturer Defendants routinely ignored the risks of hyperalgesia (a “known serious risk associated with chronic opioid analgesic therapy in which the patient becomes more sensitive to certain painful stimuli over time”); hormonal dysfunction; decline in immune function; mental clouding, confusion, and dizziness; increased falls and fractures in the elderly; neonatal abstinence syndrome (when an infant exposed to opioids prenatally suffers withdrawal after birth); and potentially fatal interactions with alcohol or with benzodiazepines (which are used to treat anxiety and may be co-prescribed with opioids, particularly to veterans suffering from pain).

304. The APF’s *Treatment Options: A Guide for People Living with Pain*, sponsored by Purdue and Cephalon, warned that risks of NSAIDs increase if “taken for more than a period of months,” with no corresponding warning about opioids. The publication falsely attributed 10,000 to 20,000 deaths annually to NSAID overdose, when the figure is closer to 3,200.

305. Janssen sponsored *Finding Relief: Pain Management for Older Adults* (2009), which listed dose limitations as “disadvantages” of other pain medicines but omitted any discussion of risks of increased doses from opioids. *Finding Relief* described the advantages and disadvantages of NSAIDs on one page, and the “myths/facts” of opioids on the facing page. The disadvantages of NSAIDs are described as involving “stomach upset or bleeding,” “kidney or liver damage if taken at high doses or for a long time,” “adverse reactions in people with asthma,” and “can increase the risk of heart attack and stroke.” The only adverse effects of opioids listed are “upset stomach or sleepiness” (which the brochure claims will go away) and constipation.

306. Endo’s NIPC website, *Painknowledge.com*, contained a flyer called “*Pain: Opioid Therapy*.” This publication listed opioids’ adverse effects but with significant omissions, including hyperalgesia, immune and hormone dysfunction, cognitive impairment, tolerance, dependence, addiction, and death.

307. The Endo-sponsored CME put on by NIPC, *Persistent Pain in the Older Adult*, discussed above, counseled that acetaminophen should be used only short-term and includes five slides on the FDA’s restrictions on acetaminophen and its adverse effects, including severe liver injury and anaphylaxis (shock). In contrast, the CME downplays the risk of opioids, claiming opioids have “possibly less potential for abuse than in younger patients,” and does not list overdose among the adverse effects. Some of those misrepresentations are described above; others are laid out below.

308. In April 2007, Endo sponsored an article aimed at prescribers, published in *Pain Medicine News*, titled “Case Challenges in Pain Management: Opioid Therapy for Chronic Pain.” The article asserted:

Opioids represent a highly effective but controversial and often misunderstood class of analgesic medications for controlling both chronic and acute pain. The

phenomenon of tolerance to opioids – the gradual waning of relief at a given dose – and fears of abuse, diversion, and misuse of these medications by patients have led many clinicians to be wary of prescribing these drugs, and/or to restrict dosages to levels that may be insufficient to provide meaningful relief.

309. To help allay these prescriber concerns, Endo emphasized the risks of NSAIDs as an alternative to opioids. The article included a case study that focused on the danger of extended use of NSAIDs, including that the subject was hospitalized with a massive upper gastrointestinal bleed believed to have resulted from his protracted NSAID use. In contrast, the article did not provide the same detail concerning the serious side effects associated with opioids.

310. Additionally, Purdue acting with Endo sponsored *Overview of Management Options*, a CME issued by the AMA in 2003, 2007, 2010, and 2013. The 2013 version remains available for CME credit. The CME taught that NSAIDs and other drugs, but not opioids, are unsafe at high doses.

311. As a result of the Manufacturer Defendants' deceptive promotion of opioids over safer and more effective drugs, opioid prescriptions increased even as the percentage of patients visiting a doctor for pain remained constant. A study of 7.8 million doctor visits between 2000 and 2010 found that opioid prescriptions increased from 11.3% to 19.6% of visits, as NSAID and acetaminophen prescriptions fell from 38% to 29%, driven primarily by the decline in NSAID prescribing.

8. Falsehood #8: OxyContin provides twelve hours of pain relief

312. Purdue also dangerously misled doctors and patients about OxyContin's duration and onset of action, making the knowingly false claim that OxyContin would provide 12 hours of pain relief for most patients. As laid out below, Purdue made this claim for two reasons. First, it provides the basis for both Purdue's patent and its market niche, allowing it to both protect and differentiate itself from competitors. Second, it allowed Purdue to imply or state outright that

OxyContin had a more even, stable release mechanism that avoided peaks and valleys and therefore the rush that fostered addiction and attracted abusers.

313. Purdue promotes OxyContin as an extended-release opioid, but the oxycodone does not enter the body on a linear rate. OxyContin works by releasing a greater proportion of oxycodone into the body upon administration, and the release gradually tapers, as illustrated in the following chart, which was apparently adapted from Purdue's own sales materials:

OxyContin PI Figure, Linear y-axis

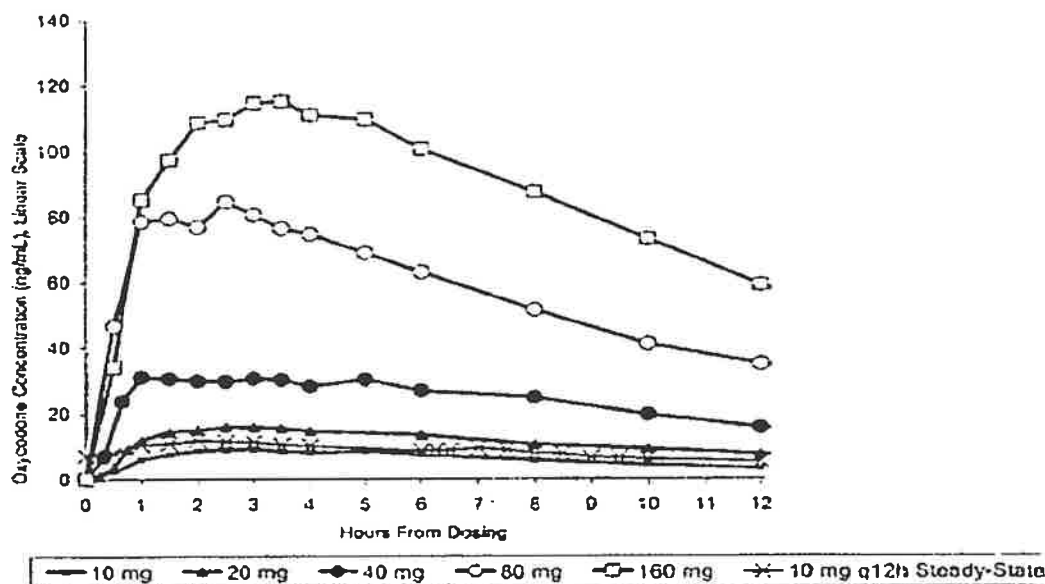


Figure 1

314. The reduced release of the drug over time means that the oxycodone no longer provides the same level of pain relief; as a result, in many patients, OxyContin does not last for the twelve hours for which Purdue promotes it—a fact that Purdue has known at all times relevant to this action.

315. OxyContin tablets provide an initial absorption of approximately 40% of the active medicine. This has a two-fold effect. First, the initial rush of nearly half of the powerful opioid

triggers a powerful psychological response. OxyContin thus behaves more like an immediate-release opioid, which Purdue itself once claimed was more addicting in its original 1995 FDA-approved drug label. Second, the initial burst of oxycodone means that there is less of the drug at the end of the dosing period, which results in the drug not lasting for a full twelve hours and precipitates withdrawal symptoms in patients, a phenomenon is known as “end of dose” failure.

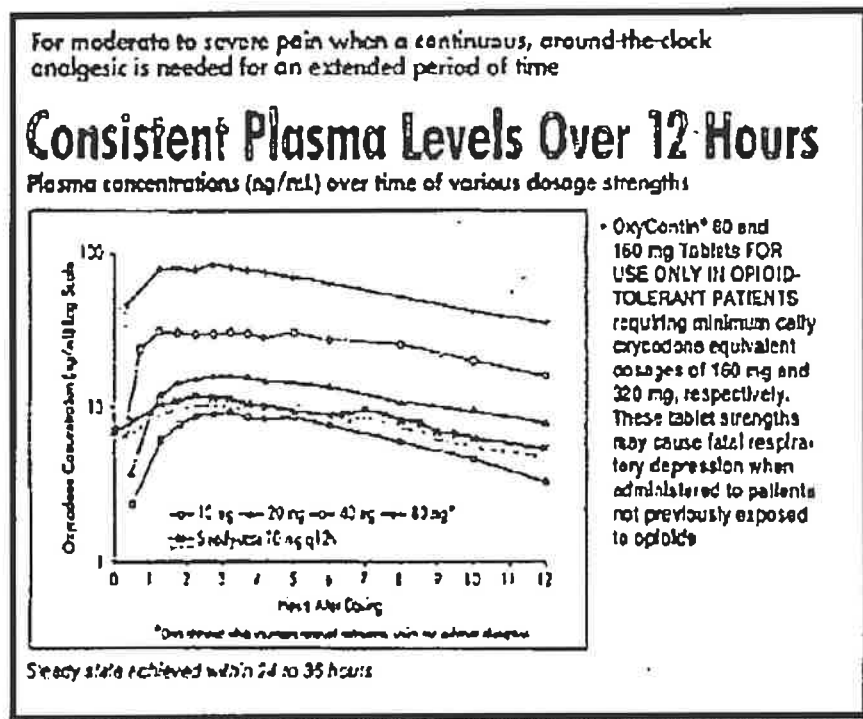
316. The FDA has found that a “substantial number” of chronic pain patients will experience end-of-dose failure with OxyContin.

317. End-of-dose failure renders OxyContin particularly dangerous because patients begin to experience withdrawal symptoms, followed by a euphoric rush with their next dose—a cycle that fuels a craving for OxyContin. For this reason, Dr. Theodore Cicero, a neuropharmacologist at the Washington University School of Medicine in St. Louis, has called OxyContin’s 12-hour dosing “the perfect recipe for addiction.” Many patients will exacerbate this cycle by taking their next dose ahead of schedule or resorting to a rescue dose of another opioid, increasing the overall amount of opioids they are taking.

318. It was Purdue’s decision to submit OxyContin for approval with 12-hour dosing. While the OxyContin label indicates that “[t]here are no well-controlled clinical studies evaluating the safety and efficacy with dosing more frequently than every 12 hours,” that is because Purdue has conducted no such studies.

319. Purdue falsely promoted OxyContin as if it were effective for a full twelve hours. Its advertising in 2000 included claims that OxyContin provides “Consistent Plasma Levels Over 12 Hours.” That claim was accompanied by a doctored version of the chart on the previous page. The doctored version deceptively minimized the rate of end-of-dose failure by depicting 10 mg in the table’s y-axis as if it were half of 100 mg. That chart, shown below, depicts the same

information as the chart above, but does so in a way that makes the absorption rate appear more consistent:



320. Purdue's 12-hour messaging was key to its competitive advantage over short-acting opioids that required patients to wake in the middle of the night to take their pills. Purdue advertisements also emphasized "Q12h" dosing. These include an advertisement in the February 2005 *Journal of Pain* and 2006 *Clinical Journal of Pain* featuring an OxyContin logo with two pill cups, reinforcing the twice-a-day message. A Purdue memo to the OxyContin launch team stated that "OxyContin's positioning statement is 'all of the analgesic efficacy of immediate-release oxycodone, with convenient q12h dosing,'" and further that "[t]he convenience of q12h dosing was emphasized as the most important benefit."

321. Purdue executives maintained the messaging of twelve-hour dosing even when many reports surfaced that OxyContin did not, in fact, last twelve hours. Instead of acknowledging

a need for more frequent dosing, Purdue instructed its representatives to push higher-strength pills, even though higher dosing carries its own risks, as noted above. It also means that patients will experience higher highs and lower lows, increasing their craving for their next pill. Nationwide, based on an analysis by the *Los Angeles Times*, more than 52% of patients taking OxyContin longer than three months are on doses greater than 60 milligrams per day—which converts to the 90 MED that the CDC Guideline urges prescribers to “avoid” or “carefully justify.”

322. The information that OxyContin did not provide pain relief for a full twelve hours was known to Purdue, and Purdue’s competitors, but was not disclosed to prescribers. Purdue’s knowledge of some pain specialists’ tendency to prescribe OxyContin three times per day instead of two was set out in Purdue’s internal documents as early as 1999 and is apparent from MEDWATCH Adverse Event reports for OxyContin.

323. Even Purdue’s competitor, Endo, was aware of the problem; Endo attempted to position its Opana ER drug as offering “durable” pain relief, which Endo understood to suggest a contrast to OxyContin. Opana ER advisory board meetings featured pain specialists citing lack of 12-hour dosing as a disadvantage of OxyContin. Endo even ran advertisements for Opana ER referring to “real” 12-hour dosing.

324. For example, in a 1996 sales strategy memo from a Purdue regional manager, the manager emphasized that representatives should “convinc[e] the physician that there is no need” for prescribing OxyContin in shorter intervals than the recommended 12-hour interval, and instead the solution is prescribing higher doses.” One sales manager instructed her team that anything shorter than 12-hour dosing “needs to be nipped in the bud. NOW!!”

325. Purdue’s failure to disclose the prevalence of end-of-dose failure meant that prescribers were misinformed about the advantages of OxyContin in a manner that preserved

Purdue's competitive advantage and profits, at the expense of patients, who were placed at greater risk of overdose, addiction, and other adverse effects.

9. *Falsehood #9: New formulations of certain opioids successfully deter abuse*

326. Rather than take the widespread abuse of and addiction to opioids as a reason to cease their untruthful marketing efforts, Manufacturer Defendants Purdue and Endo seized them as a competitive opportunity. These companies developed and oversold "abuse-deterrent formulations" ("ADF") opioids as a solution to opioid abuse and as a reason that doctors could continue to safely prescribe their opioids, as well as an advantage of these expensive branded drugs over other opioids. These Defendants' false and misleading marketing of the benefits of their ADF opioids preserved and expanded their sales and falsely reassured prescribers thereby prolonging the opioid epidemic. Other Manufacturer Defendants, including Actavis and Mallinckrodt, also promoted their branded opioids as formulated to be less addictive or less subject to abuse than other opioids.

327. The CDC Guideline confirms that "[n]o studies" support the notion that "abuse-deterrent technologies [are] a risk mitigation strategy for deterring or preventing abuse," noting that the technologies "do not prevent opioid abuse through oral intake, the most common route of opioid abuse, and can still be abused by non-oral routes." Tom Frieden, the former Director of the CDC, reported that his staff could not find "any evidence showing the updated opioids [ADF opioids] actually reduce rates of addiction, overdoses, or death."

a. Purdue's deceptive marketing of reformulated OxyContin and Hysingla ER

328. Reformulated ADF OxyContin was approved by the FDA in April 2010. It was not until 2013 that the FDA, in response to a citizen petition filed by Purdue, permitted reference to the abuse-deterrent properties in its label. When Hysingla ER (extended-release hydrocodone)

launched in 2014, the product included similar abuse-deterrent properties and limitations. But in the beginning, the FDA made clear the limited claims that could be made about ADF, noting that no evidence supported claims that ADF prevented tampering, oral abuse, or overall rates of abuse.

329. This reformulated OxyContin was introduced shortly before generic versions of OxyContin were to become available, threatening to erode Purdue's market share and the price it could charge. Purdue, however, touted its introduction of ADF opioids as evidence of its good corporate citizenship and commitment to address the problem of opioid abuse.

330. Despite its self-proclaimed good intention, Purdue merely incorporated its generally deceptive tactics with respect to ADF. Purdue sales representatives regularly overstated and misstated the evidence for and impact of the abuse-deterrent features of these opioids. Specifically, Purdue sales representatives falsely:

- a. claimed that Purdue's ADF opioids prevent tampering and that its ADFs could not be crushed or snorted;
- b. claimed that Purdue's ADF opioids reduce opioid abuse and diversion;
- c. asserted or suggested that its ADF opioids are non-addictive or less addictive,
- d. asserted or suggested that Purdue's ADF opioids are safer than other opioids, could not be abused or tampered with, and were not sought out for diversion; and
- e. failed to disclose that Purdue's ADF opioids do not impact oral abuse or misuse.

331. When pressed, Purdue acknowledged that perhaps some "extreme" patients might still abuse the drug but claimed that the ADF features protect the majority of patients. These misrepresentations and omissions are misleading and contrary to Purdue's ADF labels, Purdue's own information, and publicly available data.

332. Purdue knew or should have known that reformulated OxyContin is not more tamper-resistant than the original OxyContin and is still regularly tampered with and abused.

333. In 2009, the FDA noted, in permitting ADF labeling, that “the tamper-resistant properties will have no effect on abuse by the oral route (the most common mode of abuse).” In the 2012 medical office review of Purdue’s application to include an abuse-deterrence claim in its label for OxyContin, the FDA noted that the overwhelming majority of deaths linked to OxyContin were associated with oral consumption and only 2% of deaths were associated with recent injection and only 0.2% with snorting the drug.

334. The FDA’s Director of the Division of Epidemiology stated in September 2015 that no data that she had seen suggested the reformulation of OxyContin “actually made a reduction in abuse,” between continued oral abuse, shifts to injection of other drugs (including heroin), and the defeat of the ADF mechanism. Even Purdue’s own funded research shows that half of OxyContin abusers continued to do so orally after the reformulation rather than shift to other drugs.

335. A 2013 article presented by Purdue employees based on a review of data from poison control centers, concluded that ADF OxyContin can reduce abuse, it but ignored important negative findings. The study revealed that abuse merely shifted to other drugs and that, when the actual incidence of harmful exposures was calculated, there were *more* harmful exposures to opioids after the reformulation of OxyContin. In short, the article deceptively emphasized the advantages and ignored the disadvantages of ADF OxyContin.

336. Websites and message boards used by drug abusers, such as bluelight.org and reddit.com, report a variety of ways to tamper with OxyContin and Hysingla ER, including through grinding, microwaving then freezing, or drinking soda or fruit juice in which a tablet is dissolved. Purdue has been aware of these methods of abuse for more than a decade.

337. One-third of the patients in a 2015 study defeated the ADF mechanism and were able to continue inhaling or injecting the drug. To the extent that the abuse of Purdue's ADF opioids was reduced, there was no meaningful reduction in opioid abuse overall, as many users simply shifted to other opioids such as heroin.

338. In 2015, claiming a need to further assess its data, Purdue abruptly withdrew a supplemental new drug application related to reformulated OxyContin one day before FDA staff was to release its assessment of the application. The staff review preceded an FDA advisory committee meeting related to new studies by Purdue "evaluating the misuse and/or abuse of reformulated OxyContin" and whether those studies "have demonstrated that the reformulated product has a meaningful impact on abuse." Upon information and belief, Purdue never presented the data to the FDA because the data would not have supported claims that OxyContin's ADF properties reduced abuse or misuse.

339. Despite its own evidence of abuse, and the lack of evidence regarding the benefit of Purdue's ADF opioids in reducing abuse, Dr. Haddox, the Vice President of Health Policy for Purdue, falsely claimed in 2016 that the evidence does not show that Purdue's ADF opioids are being abused in large numbers. Purdue's recent advertisements in national newspapers also continue to claim its ADF opioids as evidence of its efforts to reduce opioid abuse, continuing to mislead prescribers, patients, payors, and the public about the efficacy of its actions.

b. Endo's deceptive marketing of reformulated Opana ER

340. As the expiration of its patent exclusivity for Opana ER neared, Endo also made abuse-deterrence a key to its marketing strategy.

341. Opana ER was particularly likely to be tampered with and abused. That is because Opana ER has lower "bioavailability" than other opioids, meaning that the active pharmaceutical ingredient (the "API" or opioid) does not absorb into the bloodstream as rapidly as other opioids

when taken orally. Additionally, when swallowed whole, the extended-release mechanism remains intact, so that only 10% of Opana ER's API is released into the patient's bloodstream relative to injection; when it is taken intranasally, that rate increases to 43%. The larger the gap between bioavailability when consumed orally versus snorting or injection, the greater the incentive for users to manipulate the drug's means of administration.

342. Endo knew by July 2011 that "some newer statistics around abuse and diversion are not favorable to our product."

343. In December 2011, Endo obtained approval for a new formulation of Opana ER that added a hard coating that the company claimed made it crush-resistant.

344. Even prior to its approval, the FDA had advised Endo that it could not market the new Opana ER as abuse-deterrent. The FDA found that such promotional claims "may provide a false sense of security since the product may be chewed and ground for subsequent abuse." In other words, Opana ER was still crushable. Indeed, Endo's own studies dating from 2009 and 2010 showed that Opana ER could be crushed and ground, and, in its correspondence with the FDA, Endo admitted that "[i]t has not been established that this new formulation of Opana ER is less subject to misuse, abuse, diversion, overdose, or addiction."

345. Further, a January 4, 2011, FDA Discipline Review letter made clear to Endo that "[t]he totality of these claims and presentations suggest that, as a result of its new formulation, Opana ER offers a therapeutic advantage over the original formulation when this has not been demonstrated by substantial evidence or substantial clinical experience. In addition, these claims misleadingly minimize the risks associated with Opana ER by suggesting that the new formulation's "INTAC" technology confers some form of abuse-deterrence properties when this has not been demonstrated by substantial evidence." Although the FDA acknowledged that there

is “evidence to support some limited improvement” provided by the new coating, it would not let Endo promote any benefit because “there are several limitations to this data.” Additionally, Endo was required to add language to its label specifically indicating that “Opana ER tablets may be abused by crushing, chewing, snorting, or injecting the product. These practices will result in less controlled delivery of the opioid and pose a significant risk to the abuser that could result in overdose and death.”

346. The FDA expressed similar concerns in nearly identical language in a May 7, 2012 letter to Endo responding to a February 2, 2012, “request ... for comments on a launch Draft Professional Detail Aid ... for Opana ER.” The FDA’s May 2012 letter also includes a full two pages of comments regarding “Omissions of material facts” that Endo left out of the promotional materials.

347. Endo consciously chose not to do any post-approval studies that might satisfy the FDA. According to internal documents, the company decided, by the time its studies would be done, generics would be on the market and “any advantages for commercials will have disappeared. However, this lack of evidence did not deter Endo from marketing Opana ER as ADF while its commercial window remained open.

348. Nonetheless, in August of 2012, Endo submitted a citizen petition asking the FDA for permission to change its label to indicate that Opana ER was abuse-resistant, both in that it was less able to be crushed and snorted and that it was resistant injection by syringe. Borrowing a page from Purdue’s playbook, Endo announced it would withdraw original Opana ER from the market and sought a determination that its decision was made for safety reasons (its lack of abuse-deterrence), which would prevent generic copies of original Opana ER.

349. Endo then sued the FDA, seeking to force expedited consideration of its citizen petition. The court filings confirmed Endo's true motives: in a declaration submitted with its lawsuit, Endo's chief operating officer indicated that a generic version of Opana ER would decrease the company's revenue by up to \$135 million per year. Endo also claimed that if the FDA did not block generic competition, \$125 million, which Endo spent on developing the reformulated drug to "promote the public welfare" would be lost. The FDA responded that: "Endo's true interest in expedited FDA consideration stems from business concerns rather than the protection of the public health."

350. Despite Endo's purported concern with public safety, not only did Endo continue to distribute original, admittedly unsafe Opana ER for nine months after the reformulated version became available, it declined to recall original Opana ER despite its dangers. In fact, Endo claimed in September 2012 to be "proud" that "almost all remaining inventory" of the original Opana ER had "been utilized."

351. In its citizen petition, Endo asserted that redesigned Opana ER had "safety advantages." Endo even relied on its rejected assertion that Opana was less crushable to argue that it developed Opana ER for patient safety reasons and that the new formulation would help, for example, "where children unintentionally chew the tablets prior to accidental ingestion."

352. However, in rejecting the petition in a 2013 decision, the FDA found that "study data show that the reformulated version's extended-release features can be compromised when subjected to ... cutting, grinding, or chewing." The FDA also determined that "reformulated Opana ER" could also be "readily prepared for injections and more easily injected[.]" In fact, the FDA warned that preliminary data—including in Endo's own studies—suggested that a higher

percentage of reformulated Opana ER abuse is via injection than was the case with the original formulation.

353. Meanwhile, in 2012, an internal memorandum to Endo account executives noted that abuse of Opana ER had “increased significantly” in the wake of the purportedly abuse-deterrent formulation. In February 2013, Endo received abuse data regarding Opana ER from Inflexxion, Inc., which gathers information from substance abusers entering treatment and reviews abuse-focused internet discussions, that confirmed continued abuse, particularly by injection.

354. In 2009, only 3% of Opana ER abuse was by intravenous means. Since the reformulation, the injection of Opana ER increased by more than 500%. Endo’s own data, presented in 2014, found between October 2012 and March 2014, 64% of abusers of Opana ER did so by injection, compared with 36% for the old formulation. The transition into the injection of Opana ER made the drug even less safe than the original formulation. The injection carries risks of HIV, Hepatitis C, and, in reformulated Opana ER’s specific case, the blood-clotting disorder thrombotic thrombocytopenic purpura (TTP), which can cause kidney failure.

355. Publicly, Endo sought to marginalize the problem. On a 2013 call with investors, when asked about an outbreak of TTP in Tennessee from injecting Opana ER, Endo sought to limit its import by assigning it to “a very, very distinct area of the country.”

356. Despite its knowledge that Opana ER was widely abused and injected, Endo marketed the drug as tamper-resistant and abuse-deterrent. Upon information and belief, based on the company’s detailing elsewhere, Endo sales representatives informed doctors that Opana ER was abuse-deterrent, could not be tampered with, and was safe. In addition, sales representatives did not disclose evidence that Opana was easier to abuse intravenously and, if pressed by

prescribers, claimed that while outlier patients might find a way to abuse the drug, most would be protected.

357. A review of national surveys of prescribers regarding their “take-aways” from pharmaceutical detailing confirms that prescribers remember being told Opana ER was tamper-resistant. Endo also tracked messages that doctors took from its in-person marketing. Among the advantages of Opana ER, according to participating doctors, was its “low abuse potential.” An internal Endo document also notes that market research showed that, “[l]ow abuse potential continues as the primary factor influencing physicians’ anticipated increase in the use of Opana ER over the next 6 months.”

358. In its written materials, Endo marketed Opana ER as having been designed to be crush-resistant, knowing that this would (falsely) imply that Opana ER actually was crush-resistant and that this crush-resistant quality would make Opana ER less likely to be abused. For example, a June 14, 2012, Endo press release announced “the completion of the company’s transition of its Opana ER franchise to the new formulation designed to be crush resistant.”

359. The press release further stated that: “We firmly believe that the new formulation of Opana ER, coupled with our long-term commitment to awareness and education around appropriate use of opioids will benefit patients, physicians, and payers. The press release described the old formulation of Opana as subject to abuse and misuse but failed to disclose the absence of evidence that reformulated Opana was any better. In September 2012, another Endo press release stressed that reformulated Opana ER employed “INTAC Technology” and continued to describe the drug as “designed to be crush-resistant.”

360. Similarly, journal advertisements that appeared in April 2013 stated Opana ER was “designed to be crush resistant.” A January 2013 article in Pain Medicine News, based in part on

an Endo press release, described Opana ER as “crush-resistant.” This article was posted on the *Pain Medicine News* website, which was accessible to patients and prescribers.

361. In March 2017, because Opana ER could be “readily prepared for injection” and was linked to outbreaks of HIV and TTP, an FDA advisory committee recommended that Opana be withdrawn from the market. The FDA adopted this recommendation on June 8, 2017. Endo announced on July 6, 2017, that it would agree to stop marketing and selling Opana ER. However, by this point, the damage had been done. Even then, Endo continued to insist, falsely, that it “has taken significant steps over the years to combat misuse and abuse.”

c. Other Manufacturer Defendants’ misrepresentations regarding abuse deterrence

362. A guide for prescribers under Actavis’s copyright deceptively represents that Kadian is more difficult to abuse and less addictive than other opioids. The guide declares that “unique pharmaceutical formulation of KADIAN may offer some protection from the extraction of morphine sulfate for intravenous use by illicit users,” and “KADIAN may be less likely to be abused by health care providers and illicit users” because of its “[s]low onset of action.” Kadian, however, was not approved by the FDA as abuse-deterrent, and, upon information and belief, Actavis had no studies to suggest it was.

363. Mallinckrodt promoted both Exalgo (extended-release hydromorphone) and Xartemis XR (oxycodone and acetaminophen) as specifically formulated to reduce abuse. For example, Mallinckrodt’s promotional materials stated that “the physical properties of EXALGO may make it difficult to extract the active ingredient using common forms of physical and chemical tampering, including chewing, crushing and dissolving.” One member of the FDA’s Controlled Substance Staff, however, noted in 2010 that hydromorphone has “a high abuse potential comparable to oxycodone” and further stated that “we predict that Exalgo will have high levels of abuse and diversion.”

364. With respect to Xartemis XR, Mallinckrodt's promotional materials stated that "XARTEMIS XR has technology that requires abusers to exert additional effort to extract the active ingredient from the large quantity of inactive and deterrent ingredients." In anticipation of Xartemis XR's approval, Mallinckrodt added 150-200 sales representatives to promote it, and CEO Mark Trudeau said the drug could generate "hundreds of millions in revenue."

365. While Manufacturer Defendants promote patented technology as the solution to opioid abuse and addiction, none of their "technology" addresses the most common form of abuse—oral ingestion—and their statements regarding abuse-deterrent formulations give the misleading impression that these reformulated opioids can be prescribed safely.

366. In sum, each of the nine categories of misrepresentations discussed above regarding the use of opioids to treat chronic pain was not supported by or was contrary to the scientific evidence. In addition, the misrepresentations and omissions set forth above and elsewhere in this Complaint are misleading and contrary to the Manufacturer Defendants' products' labels.

B. The Manufacturer Defendants Disseminated Their Misleading Messages About Opioids Through Multiple Channels

367. The Manufacturer Defendants' false marketing campaign not only targeted the medical community who had to treat chronic pain, but also patients who experience chronic pain.

368. The Manufacturer Defendants utilized various channels to carry out their marketing scheme of targeting the medical community and patients with deceptive information about opioids: (1) Front Groups with the false appearance of independence from the Manufacturer Defendants; (2) KOLs, that is, doctors who were paid by the Manufacturer Defendants to promote their pro-opioid message; (3) CME programs controlled and/or funded by the Manufacturer Defendants; (4) branded advertising; (5) unbranded advertising; (6) publications; (7) direct, targeted communications with prescribers by sales representatives; and (8) speakers bureaus and programs.

1. The Manufacturer Defendants Directed Front Groups to Deceptively Promote Opioid Use

369. Patient advocacy groups and professional associations also became vehicles to reach prescribers, patients, and policymakers. Manufacturer Defendants exerted influence and effective control over the messaging by these groups by providing major funding directly to them, as well as through KOLs who served on their boards. These Front Groups put outpatient education materials, treatment guidelines and CMEs that supported the use of opioids for chronic pain, overstated their benefits and understated their risks. Defendants funded these Front Groups in order to ensure supportive messages from these seemingly neutral and credible third parties, and their funding did, in fact, ensure such supportive messages—often at the expense of their own constituencies.

370. Patient advocacy organizations and professional societies like the Front Groups play a significant role in shaping health policy debates, setting national guidelines for patient treatment, raising disease awareness, and educating the public. Even small organizations—with their large numbers and credibility with policymakers and the public—have extensive influence in specific disease areas. Larger organizations with extensive funding and outreach capabilities likely have a substantial effect on policies relevant to their industry sponsors.

371. The Manufacturer Defendants made millions of dollars' worth of contributions to various Front Groups.

372. The Manufacturer Defendants also “made substantial payments to individual group executives, staff members, board members, and advisory board members” affiliated with the Front Groups.

373. The Front Groups amplified or issued messages that reinforced industry efforts to promote opioid prescription and use, including guidelines and policies minimizing the risk of

addiction and promoting opioids for chronic pain. They also lobbied to change laws directed at curbing opioid use, strongly criticized landmark CDC guidelines on opioid prescribing, and challenged legal efforts to hold physicians and industry executives responsible for over-prescription and misbranding.

374. The Manufacturer Defendants took an active role in guiding, reviewing, and approving many of the false and misleading statements issued by the Front Groups, ensuring that Defendants were consistently in control of their content. By funding, directing, editing, approving, and distributing these materials, Defendants exercised control over and adopted their false and deceptive messages and acted in concert with the Front Groups and through the Front Groups, with each other to deceptively promote the use of opioids for the treatment of chronic pain.

a. American Pain Foundation

375. The most prominent of the Front Groups was the American Pain Foundation (“APF”). While APF held itself out as an independent patient advocacy organization, in reality, it received 90% of its funding in 2010 from the drug and medical-device industry, including from defendants Purdue, Endo, Janssen, and Cephalon. APF received more than \$10 million in funding from opioid manufacturers from 2007 until it closed its doors in May 2012. By 2011, APF was entirely dependent on incoming grants from Defendants Purdue, Cephalon, Endo, and others to avoid using its line of credit. Endo was APF’s largest donor and provided more than half of its \$10 million in funding from 2007 to 2012.

376. For example, APF published a guide sponsored by Cephalon and Purdue titled *Treatment Options: A Guide for People Living with Pain* and distributed 17,200 copies of this guide in one year alone, according to its 2007 annual report. This guide contains multiple misrepresentations regarding opioid use, which are discussed below.

377. APF also developed the National Initiative on Pain Control (“NIPC”), which ran a facially unaffiliated website, www.painknowledge.com. NIPC promoted itself as an education initiative led by its expert leadership team, including purported experts in the pain management field. NIPC published unaccredited prescriber education programs (accredited programs are reviewed by a third party and must meet certain requirements of independence from pharmaceutical companies), including a series of “dinner dialogues.” But Endo substantially controlled NIPC, by funding NIPC projects, developing, specifying, and reviewing its content, and distributing NIPC materials. Endo’s control of NIPC was such that Endo listed it as one of its “professional education initiative[s]” in a plan Endo submitted to the FDA. Yet, Endo’s involvement in NIPC was nowhere disclosed on the website pages describing NIPC or www.painknowledge.org. Endo estimated it would reach 60,000 prescribers through NIPC.

378. APF was often called upon to provide “patient representatives” for the Manufacturer Defendants’ promotional activities, including for Purdue’s “Partners Against Pain” and Janssen’s “Let’s Talk Pain.” Although APF presented itself as a patient advocacy organization, it functioned largely as an advocate for the interests of the Manufacturer Defendants, not patients. As Purdue told APF in 2001, the basis of a grant to the organization was Purdue’s desire to strategically align its investments in nonprofit organizations that share [its] business interests.

379. In practice, APF operated in close collaboration with Defendants, submitting grant proposals seeking to fund activities and publications suggested by Defendants and assisting in marketing projects for Defendants.

380. This alignment of interests was expressed most forcefully in the fact that Purdue hired APF to provide consulting services on its marketing initiatives. Purdue and APF entered into a “Master Consulting Services” Agreement on September 14, 2011. That agreement gave

Purdue substantial rights to control APF's work related to a specific promotional project. Moreover, based on the assignment of particular Purdue "contacts" for each project and APF's periodic reporting on their progress, the agreement enabled Purdue to be regularly aware of the misrepresentations APF was disseminating regarding the use of opioids to treat chronic pain in connection with that project. The agreement gave Purdue—but not APF—the right to end the project (and, thus, APF's funding) for any reason. Even for projects not produced during the terms of this Agreement, the Agreement demonstrates APF's lack of independence and willingness to harness itself to Purdue's control and commercial interests, which would have carried across all of APF's work.

381. APF's Board of Directors was largely comprised of doctors who were on the Manufacturer Defendants' payrolls, either as consultants or speakers at medical events. The close relationship between APF and the Manufacturer Defendants demonstrates APF's clear lack of independence in its finances, management, and mission and its willingness to allow Manufacturer Defendants to control its activities and messages supports an inference that each Defendant that worked with it was able to exercise editorial control over its publications—even when Defendants' messages contradicted APF's internal conclusions. For example, a roundtable convened by APF and funded by Endo also acknowledged the lack of evidence to support chronic opioid therapy. APF's formal summary of the meeting notes concluded that: "[An] important barrier[] to appropriate opioid management [is] the lack of confirmatory data about the long-term safety and efficacy of opioids in non-cancer chronic pain, amid cumulative clinical evidence."

382. In May 2012, the U.S. Senate Finance Committee began looking into APF to determine the links, financial and otherwise, between the organization and the manufacturers of opioid painkillers. Within days of being targeted by the Senate investigation, APF's board voted

to dissolve the organization “due to irreparable economic circumstances.” APF then “cease[d] to exist, effective immediately.” Without support from Manufacturer Defendants, to whom APF could no longer be helpful, APF was no longer financially viable.

b. American Academy of Pain Medicine and the American Pain Society

383. The American Academy of Pain Medicine (“AAPM”) and the American Pain Society (“APS”) are professional medical societies, each of which received substantial funding from Defendants from 2009 to 2013. In 1997, AAPM issued a “consensus” statement that endorsed opioids to treat chronic pain and claimed that the risk that patients would become addicted to opioids was low. The Chair of the committee that issued the statement, Dr. Haddox, was at the time a paid speaker for Purdue. The sole consultant to the committee was Dr. Russell Portenoy (“Dr. Portenoy”), who was also a spokesperson for Purdue. The consensus statement, which also formed the foundation of the 1998 Guidelines, was published on the AAPM’s website.

384. AAPM’s corporate council includes Purdue, Depomed, Teva, and other pharmaceutical companies. AAPM’s past presidents include Dr. Haddox (1998), Dr. Fishman (2005), Dr. Perry G. Fine (“Dr. Fine”) (a KOL discussed below) (2011) and Dr. Webster (2013), all of whose connections to the opioid manufacturers are well-documented as set forth below.

385. Fishman, who also served as a KOL for Manufacturer Defendants, stated that he would place the organization “at the forefront” of teaching that “the risks of addiction are ... small and can be managed.”

386. AAPM received over \$2.2 million in funding since 2009 from opioid manufacturers. AAPM maintained a corporate relations council, whose members paid \$25,000 per year (on top of other funding) to participate. The benefits included allowing members to present educational programs at off-site dinner symposia in connection with AAPM’s marquee event – its annual meeting held in Palm Springs, California, or other resort locations.

387. AAPM describes the annual event as an “exclusive venue” for offering CMEs to doctors. Membership in the corporate relations council also allows drug company executives and marketing staff to meet with AAPM executive committee members in small settings. Defendants Endo, Purdue, and Cephalon were members of the council and presented deceptive programs to doctors who attended this annual event. The conferences sponsored by AAPM heavily emphasized CME sessions on opioids – 37 out of roughly 40 at one conference alone.

388. AAPM’s staff understood that they and their industry funders were engaged in a common task. Defendants were able to influence AAPM through both their significant and regular funding and the leadership of pro-opioid KOLs within the organization.

389. AAPM and APS issued their own guidelines in 2009 (“2009 Guidelines”). AAPM, with the assistance, prompting, involvement, and funding of Defendants, issued the treatment guidelines discussed herein and continued to recommend the use of opioids to treat chronic pain. Fourteen of the 21 panel members who drafted the 2009 Guidelines, including KOL Dr. Fine, received support from Defendants Janssen, Cephalon, Endo, and Purdue. Of these individuals, six received support from Purdue, eight from Teva, nine from Janssen, and nine from Endo.

390. One panel member, Dr. Joel Saper, Clinical Professor of Neurology at Michigan State University and founder of the Michigan Headache & Neurological Institute, resigned from the panel because of his concerns that the guidelines were influenced by contributions that drug companies, including Purdue, Endo, Janssen, and Teva, made to the sponsoring organizations and committee members.

391. Dr. Gilbert Fanciullo, now retired as a professor at Dartmouth College’s Geisel School of Medicine, who also served on the AAPM/APS Guidelines panel, has since described them as “skewed” by drug companies and “biased in many important respects,” including the high

presumptive maximum dose, lack of suggested mandatory urine toxicology testing, and claims of a low risk of addiction.

392. The 2009 Guidelines have been a particularly effective channel of deception. They have influenced not only treating physicians, but also the scientific literature on opioids; they were reprinted in the *Journal of Pain*, have been cited hundreds of times in academic literature, were disseminated during the relevant time period, and were and are available online. Treatment guidelines are especially influential with primary care physicians and family doctors to whom Manufacturer Defendants promoted opioids, whose lack of specialized training in pain management and opioids makes them more reliant on, and less able to evaluate, these guidelines. For that reason, the CDC has recognized that treatment guidelines can “change prescribing practices.”

393. The 2009 Guidelines are relied upon by doctors, especially general practitioners and family doctors who have no specific training in treating chronic pain.

394. The Manufacturer Defendants widely cited and promoted the 2009 Guidelines without disclosing the lack of evidence to support their conclusions, their involvement in the development of the Guidelines, or their financial backing of the authors of these Guidelines. For example, a speaker presentation prepared by Endo in 2009 titled *The Role of Opana ER in the Management of Moderate to Severe Chronic Pain* relies on the AAPM/APS Guidelines while omitting their disclaimer regarding the lack of evidence for recommending the use of opioids for chronic pain.

c. Federation of State Medical Boards

395. The Federation of State Medical Boards (“FSMB”) is a trade organization representing the various state medical boards in the United States. The state boards that comprise

the FSMB membership have the power to license doctors, investigate complaints, and discipline physicians.

396. The FSMB finances opioid- and pain-specific programs through grants from Defendants.

397. Since 1998, the FSMB has been developing treatment guidelines for the use of opioids for the treatment of pain. The 1998 version, Model Guidelines for the Use of Controlled Substances for the Treatment of Pain (“1998 Guidelines”) was produced “in collaboration with pharmaceutical companies.” The 1998 Guidelines that the pharmaceutical companies helped author taught not that opioids could be appropriate in only limited cases after other treatments had failed, but that opioids were “essential” for treatment of chronic pain, including as a first prescription option.

398. A 2004 iteration of the 1998 Guidelines and the 2007 book, *Responsible Opioid Prescribing*, also made the same claims as to the 1998 Guidelines. These guidelines were posted online and were available to and intended to reach physicians nationwide, including in Plaintiff’s Community.

399. FSMB’s 2007 publication *Responsible Opioid Prescribing* was backed largely by drug manufacturers, including Purdue, Endo, and Cephalon. The publication also received support from the American Pain Foundation and the AAPM. The publication was written by Dr. Fishman, and Dr. Fine served on the Board of Advisors. In all, 163,131 copies of *Responsible Opioid Prescribing* were distributed by state medical boards (and through the boards, to practicing doctors). The FSMB website describes the book as “the leading continuing medical education (CME) activity for prescribers of opioid medications.” This publication asserted that opioid therapy to relieve pain and improve function is a legitimate medical practice for acute and chronic

pain of both cancer and non-cancer origins; that pain is under-treated, and that patients should not be denied opioid medications except in light of clear evidence that such medications are harmful to the patient.

400. The Manufacturer Defendants relied on the 1998 Guidelines to convey the alarming message that “under-treatment of pain” would result in official discipline, but no discipline would result if opioids were prescribed as part of an ongoing patient relationship and prescription decisions were documented. FSMB turned doctors’ fear of discipline on its head: doctors, who used to believe that they would be disciplined if their patients became addicted to opioids, were taught instead that they would be punished if they failed to prescribe opioids to their patients with chronic pain.

d. The Alliance for Patient Access

401. Founded in 2006, the Alliance for Patient Access (“APA”) is a self-described patient advocacy and health professional organization that styles itself as “a national network of physicians dedicated to ensuring patient access to approved therapies and appropriate clinical care.” It is run by Woodberry Associates LLC, a lobbying firm that was also established in 2006. As of June 2017, the APA listed 30 “Associate Members and Financial Supporters.” The list includes J&J (parent of Janssen), Endo, Mallinckrodt, Purdue, and Cephalon. References herein to APA include two affiliated groups: the Global Alliance for Patient Access and the Institute for Patient Access.

402. APA’s board members have also directly received substantial funding from pharmaceutical companies. For instance, board vice president Dr. Srinivas Nalamachu (“Dr. Nalamachu”), who practices in Kansas, received more than \$800,000 from 2013 through 2015 from pharmaceutical companies—nearly all of it from manufacturers of opioids or drugs that treat opioids’ side effects, including from defendants Endo, Insys, Purdue, and Cephalon. Dr.

Nalamachu's clinic was raided by FBI agents in connection with an investigation of Insys and its payment of kickbacks to physicians who prescribed Subsys. Other board members include Dr. Robert A. Yapundich from North Carolina, who received \$215,000 from 2013 through 2015 from pharmaceutical companies, including payments by defendants Cephalon and Mallinckrodt; Dr. Jack D. Schim from California, who received more than \$240,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Mallinckrodt, and Cephalon; Dr. Howard Hoffberg from Maryland, who received \$153,000 between 2013 and 2015 from pharmaceutical companies, including defendants Endo, Purdue, Insys, Mallinckrodt and Cephalon; and Dr. Robin K. Dore from California, who received \$700,000 between 2013 and 2015 from pharmaceutical companies.

403. Among its activities, APA issued a "white paper" titled "Prescription Pain Medication: Preserving Patient Access While Curbing Abuse." Among other things, the white paper criticizes prescription monitoring programs, purporting to express concern that they are burdensome, not user-friendly, and of questionable efficacy:

Prescription monitoring programs that are difficult to use and cumbersome can place substantial burdens on physicians and their staff, ultimately leading many to stop prescribing pain medications altogether. This forces patients to seek pain relief medications elsewhere, which may be much less convenient and familiar and may even be dangerous or illegal.

In some states, physicians who fail to consult prescription monitoring databases before prescribing pain medications for their patients are subject to fines; those who repeatedly fail to consult the databases face loss of their professional licensure. Such penalties seem excessive and may inadvertently target older physicians in rural areas who may not be facile with computers and may not have the requisite office staff. Moreover, threatening and fining physicians in an attempt to induce compliance with prescription monitoring programs represents a system based on punishment as opposed to incentives

We cannot merely assume that these programs will reduce prescription pain medication use and abuse.

404. The white paper also purports to express concern about policies that have been enacted in response to the prevalence of pill mills:

Although well-intentioned, many of the policies designed to address this problem have made it difficult for legitimate pain management centers to operate. For instance, in some states, [pain management centers] must be owned by physicians or professional corporations must have a Board-certified medical director, may need to pay for annual inspections and are subject to increased record keeping and reporting requirements [I]t is not even certain that the regulations are helping prevent abuses.

405. In addition, in an echo of earlier industry efforts to push back against what they termed “opiophobia,” the white paper laments the stigma associated with prescribing and taking pain medication:

Both pain patients and physicians can face negative perceptions and outright stigma. When patients with chronic pain can’t get their prescriptions for pain medication filled at a pharmacy, they may feel like they are doing something wrong—or even criminal Physicians can face similar stigma from peers. Physicians in non-pain specialty areas often look down on those who specialize in pain management—a situation fueled by the numerous regulations and fines that surround prescription pain medications.

406. In conclusion, the white paper states that “[p]rescription pain medications, and specifically the opioids, can provide substantial relief for people who are recovering from surgery, afflicted by chronic painful diseases, or experiencing pain associated with other conditions that does not adequately respond to over-the-counter drugs.”

407. The APA also issues “Patient Access Champion” financial awards to members of Congress, including 50 such awards in 2015. The awards were funded by a \$7.8 million donation from unnamed donors. While the awards are ostensibly given for protecting patients’ access to Medicare and are thus touted by their recipients as demonstrating a commitment to protecting the rights of senior citizens and the middle class, they appear to be given to provide cover to and reward members of Congress who have supported the APA’s agenda.

408. The APA also lobbies Congress directly. In 2015, the APA signed onto a letter supporting legislation proposed to limit the ability of the DEA to police pill mills by enforcing the “suspicious orders” provision of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §801 *et seq.* (“CSA” or “Controlled Substances Act”). The AAPM is also a signatory to this letter. An internal U.S. Department of Justice (“DOJ”) memo stated that the proposed bill “‘could actually result in increased diversion, abuse, and public health and safety consequences’” and, according to DEA chief administrative law judge John J. Mulrooney (“Mulrooney”), the law would make it “all but logically impossible” to prosecute manufacturers and distributors, like the defendants here, in the federal courts. The law passed both houses of Congress and was signed into law in 2016.

e. The U.S. Pain Foundation

409. The U.S. Pain Foundation (“USPF”) was another Front Group with systematic connections and interpersonal relationships with the Manufacturer Defendants. The USPF was one of the largest recipients of contributions from the Manufacturer Defendants, collecting nearly \$3 million in payments between 2012 and 2015 alone. The USPF was also a critical component of the Manufacturer Defendants’ lobbying efforts to reduce the limits on over-prescription. The U.S. Pain Foundation advertises its ties to the Manufacturer Defendants, listing opioid manufacturers like Pfizer, Teva, Depomed, Endo, Purdue, McNeil (i.e. Janssen), and Mallinckrodt as “Platinum,” “Gold,” and “Basic” corporate members. Industry Front Groups like the American Academy of Pain Management, the AAPM, the APS, and PhRMA are also members of varying levels in the USPF.

f. American Geriatrics Society

410. The American Geriatrics Society (“AGS”) was another Front Group with systematic connections and interpersonal relationships with the Manufacturer Defendants. The

AGS was a large recipient of contributions from the Manufacturer Defendants, including Endo, Purdue, and Janssen. AGS contracted with Purdue, Endo and Janssen to disseminate guidelines regarding the use of opioids for chronic pain in 2002 (The Management of Persistent Pain in Older Persons, hereinafter “2002 AGS Guidelines”) and 2009 (Pharmacological Management of Persistent Pain in Older Persons, hereinafter “2009 AGS Guidelines”). According to news reports, AGS has received at least \$344,000 in funding from opioid manufacturers since 2009. AGS’s complicity in the common purpose with the Manufacturer Defendants is evidenced by the fact that AGS internal discussions in August 2009 reveal that it did not want to receive-up front funding from drug companies, which would suggest drug company influence but would instead accept commercial support to disseminate pro-opioid publications.

411. The 2009 AGS Guidelines recommended that “[a]ll patients with moderate to severe pain ... should be considered for opioid therapy.” The panel made “strong recommendations” in this regard despite “low quality of evidence” and concluded that the risk of addiction is manageable for patients, even with a prior history of drug abuse. These Guidelines further recommended that “the risks [of addiction] are exceedingly low in older patients with no current or past history of substance abuse.” These recommendations are not supported by any study or other reliable scientific evidence. Nevertheless, they have been cited over 1,833 times in Google Scholar (which allows users to search scholarly publications that would be have been relied on by researchers and prescribers) since their 2009 publication and as recently as this year.

412. Representatives of the Manufacturer Defendants, often at informal meetings at conferences, suggested activities, lobbying efforts and publications for AGS to pursue. AGS then submitted grant proposals seeking to fund these activities and publications, knowing that drug companies would support projects conceived as a result of these communications.

413. Members of AGS Board of Directors were doctors who were on the Manufacturer Defendants' payrolls, either as consultants or speakers at medical events. As described below, many of the KOLs also served in leadership positions within the AGS.

2. *The Manufacturer Defendants Paid KOLs to Deceptively Promote Opioid Use*

414. To falsely promote their opioids, the Manufacturer Defendants paid and cultivated a select circle of doctors who were chosen and sponsored by the Manufacturer Defendants for their supportive messages. As set forth below, pro-opioid doctors have been at the hub of the Manufacturer Defendants' well-funded, pervasive marketing scheme since its inception and were used to create the grave misperception science and legitimate medical professionals favored the wider and broader use of opioids. These doctors include Dr. Portenoy and Dr. Webster, as set forth in this section, as well as Dr. Fine and Dr. Fishman, as set forth further below.

415. Although these KOLs were funded by the Manufacturer Defendants, the KOLs were used extensively to present the appearance that unbiased and reliable medical research supporting the broad use of opioid therapy for chronic pain had been conducted and was being reported on by independent medical professionals.

416. As the Manufacturer Defendants' false marketing scheme picked up steam, this pro-opioid KOLs wrote, consulted on, edited, and lent their names to books and articles, and gave speeches and CMEs supportive of opioid therapy for chronic pain. They served on committees that developed treatment guidelines that strongly encouraged the use of opioids to treat chronic pain and they were placed on boards of pro-opioid advocacy groups and professional societies that develop, select, and present CMEs.

417. Through the use of their KOLs and strategic placement of these KOLs throughout every critical distribution channel of information within the medical community, the Manufacturer

Defendants were able to exert control of each of these modalities through which doctors receive their information.

418. In return for their pro-opioid advocacy, the Manufacturer Defendants' KOLs received money, prestige, recognition, research funding, and avenues to publish. For example, Dr. Webster has received funding from Endo, Purdue, and Cephalon. Dr. Fine has received funding from Janssen, Cephalon, Endo, and Purdue.

419. The Manufacturer Defendants carefully vetted their KOLs to ensure that they were likely to remain on-message and supportive of the Manufacturer Defendants' agenda. The Manufacturer Defendants also kept close tabs on the content of the materials published by these KOLs. And, of course, the Manufacturer Defendants kept these KOLs well-funded to enable them to push the Manufacturer Defendants' deceptive message out to the medical community.

420. Once the Manufacturer Defendants identified and funded KOLs and those KOLs began to publish "scientific" papers supporting the Manufacturer Defendants' false position that opioids were safe and effective for treatment of chronic pain, the Manufacturer Defendants poured significant funds and resources into a marketing machine that widely cited and promoted their KOLs and studies or articles by their KOLs to drive prescription of opioids for chronic pain. The Manufacturer Defendants cited to, distributed, and marketed these studies and articles by their KOLs as if they were independent medical literature so that it would be well-received by the medical community. By contrast, the Manufacturer Defendants did not support, acknowledge, or disseminate the truly independent publications of doctors critical of the use of chronic opioid therapy.

421. In their promotion of the use of opioids to treat chronic pain, the Manufacturer Defendants' KOLs knew that their statements were false and misleading, or they recklessly

disregarded the truth in doing so, but they continued to publish their misstatements to benefit themselves and the Manufacturer Defendants.

a. Dr. Portenoy

422. In 1986, Dr. Portenoy, who later became Chairman of the Department of Pain Medicine and Palliative Care at Beth Israel Medical Center in New York while at the same time serving as a top spokesperson for drug companies, published an article reporting that “[f]ew substantial gains in employment or social function could be attributed to the institution of opioid therapy.”

423. Writing in 1994, Dr. Portenoy described the prevailing attitudes regarding the dangers of long-term use of opioids:

The traditional approach to chronic non-malignant pain does not accept the long-term administration of opioid drugs. This perspective has been justified by the perceived likelihood of tolerance, which would attenuate any beneficial effects over time, and the potential for side effects, worsening disability, and addiction. According to conventional thinking, the initial response to an opioid drug may appear favorable, with partial analgesia and salutary mood changes, but adverse effects inevitably occur thereafter. It is assumed that the motivation to improve function will cease as mental clouding occurs and the belief takes hold that the drug can, by itself, return the patient to a normal life. Serious management problems are anticipated, including difficulty in discontinuing a problematic therapy and the development of drug-seeking behavior induced by the desire to maintain analgesic effects, avoid withdrawal, and perpetuate reinforcing psychic effects. There is an implicit assumption that little separates these outcomes from the highly aberrant behaviors associated with addiction.

(emphasis added). According to Dr. Portenoy, the foregoing problems could constitute “compelling reasons to reject long-term opioid administration as a therapeutic strategy in all but the most desperate cases of chronic nonmalignant pain.”

424. Despite having taken this position on long-term opioid treatment, Dr. Portenoy ended up becoming a spokesperson for Purdue and other Manufacturer Defendants, promoting the use of prescription opioids and minimizing their risks. A respected leader in the field of pain

treatment, Dr. Portenoy was highly influential. Dr. Andrew Kolodny, a co-founder of Physicians for Responsible Opioid Prescribing, described him “lecturing around the country as a religious-like figure. The megaphone for Portenoy is Purdue, which flies in people to resorts to hear him speak. It was a compelling message: ‘Docs have been letting patients suffer; nobody really gets addicted; it’s been studied.’”

425. As one organizer of CME seminars who worked with Dr. Portenoy and Purdue pointed out, “had Portenoy not had Purdue’s money behind him, he would have published some papers, made some speeches, and his influence would have been minor. With Purdue’s millions behind him, his message, which dovetailed with their marketing plans, was hugely magnified.”

426. Dr. Portenoy was also a critical component of the Manufacturer Defendants’ control over their Front Groups. Specifically, Dr. Portenoy sat as a Director on the board of the APF. He was also the President of the APS.

427. In recent years, some of the Manufacturer Defendants’ KOLs have conceded that many of their past claims in support of opioid use lacked evidence or support in the scientific literature. Dr. Portenoy has now admitted that he minimized the risks of opioids and that he “gave innumerable lectures in the late 1980s and ‘90s about addiction that weren’t true.” He mused, “Did I teach about pain management, specifically about opioid therapy, in a way that reflects misinformation? Well, against the standards of 2012, I guess I did”

428. In a 2011 interview released by Physicians for Responsible Opioid Prescribing, Portenoy stated that his earlier work purposefully relied on evidence that was not “real” and left real evidence behind:

I gave so many lectures to primary care audiences in which the Porter and Jick article was just one piece of data that I would then cite, and I would cite six, seven, maybe ten different avenues of thought or avenues of evidence, *none of which represented real evidence*, and yet what I was trying to do was to create a narrative

so that the primary care audience would look at this information in [total] and feel more comfortable about opioids in a way they hadn't before. *In essence, this was education to destigmatize [opioids], and because the primary goal was to destigmatize, we often left evidence behind.*

429. Several years earlier, when interviewed by journalist Barry Meier for his 2003 book, *Pain Killer*, Dr. Portenoy was more direct: "It was pseudoscience. I guess I'm going to have always to live with that one."

b. Dr. Webster

430. Another KOL, Dr. Webster, was the co-founder and Chief Medical Director of the Lifetree Clinical Research & Pain Clinic in Salt Lake City, Utah. Dr. Webster was President in 2013 and is a current board member of AAPM, a Front Group that ardently supports chronic opioid therapy. He is a Senior Editor of *Pain Medicine*, the same journal that published Endo's special advertising supplements touting Opana ER. Dr. Webster was the author of numerous CMEs sponsored by Cephalon, Endo, and Purdue. At the same time, Dr. Webster was receiving significant funding from Defendants (including nearly \$2 million from Cephalon).

431. Dr. Webster created and promoted the Opioid Risk Tool, a five-question, one-minute screening tool relying on patient self-reports that purportedly allows doctors to manage the risk that their patients will become addicted to or abuse opioids. The claimed ability to pre-sort patients likely to become addicted is an important tool in giving doctors the confidence to prescribe opioids long-term, and for this reason, references to screening appear in various industry-supported guidelines. Versions of Dr. Webster's Opioid Risk Tool ("ORT") appear on, or are linked to, websites run by Endo, Janssen, and Purdue. In 2011, Dr. Webster presented, via webinar, a program sponsored by Purdue titled, *Managing Patient's Opioid Use: Balancing the Need and the Risk*. Dr. Webster recommended the use of risk screening tools, urine testing, and patient

agreements to prevent “overuse of prescriptions” and “overdose deaths.” This webinar was available to and was intended to reach doctors in Cuyahoga County.

432. Dr. Webster was himself tied to numerous overdose deaths. He and the Lifetree Clinic were investigated by the DEA for overprescribing opioids after twenty patients died from overdoses. In keeping with the Manufacturer Defendants’ promotional messages, Dr. Webster apparently believed the solution to patients’ tolerance or addictive behaviors was more opioids: he prescribed staggering quantities of pills.

433. At an AAPM annual meeting held February 22 through 25, 2006, Cephalon sponsored a presentation by Dr. Webster and others titled, “Open-label study of fentanyl effervescent buccal tablets in patients with chronic pain and breakthrough pain: Interim safety results.” The presentation’s agenda description states: “Most patients with chronic pain experience episodes of breakthrough pain, yet no currently available pharmacologic agent is ideal for its treatment.” The presentation purports to cover a study analyzing the safety of a new form of fentanyl buccal tablets in the chronic pain setting and promises to show the “[i]nterim results of this study suggest that FEBT is safe and well-tolerated in patients with chronic pain and BTP.” This CME effectively amounted to off-label promotion of Cephalon’s opioids—the only drugs in this category—for chronic pain, even though they were approved only for cancer pain.

434. Cephalon sponsored a CME written by Dr. Webster, *Optimizing Opioid Treatment for Breakthrough Pain*, offered by Medscape, LLC from September 28, 2007, through December 15, 2008. The CME taught that non-opioid analgesics and combination opioids containing non-opioids such as aspirin and acetaminophen are less effective at treating breakthrough pain because of dose limitations on the non-opioid component.

c. Dr. Fine

435. Dr. Fine's ties to the Manufacturer Defendants have been well documented. He has authored articles and testified in court cases and before state and federal committees, and he, too, has argued against legislation restricting high-dose opioid prescriptions for non-cancer patients. He has served on Purdue's advisory board, provided medical-legal consulting for Janssen, and participated in CME activities for Endo, along with serving in these capacities for several other drug companies. He co-chaired the APS-AAPM Opioid Guideline Panel, served as treasurer of the AAPM from 2007 to 2010 and as president of that group from 2011 to 2013, and was also on the board of directors of APF.

436. Multiple videos feature Fine delivering educational talks about prescription opioids. He even testified at trial that the 1,500 pills a month prescribed to celebrity Anna Nicole Smith for pain did not make her an addict before her death of a drug overdose.

437. He has also acknowledged having failed to disclose numerous conflicts of interest. For example, Dr. Fine failed to fully disclose payments received as required by his employer, the University of Utah—telling the university that he had received under \$5,000 in 2010 from J&J for providing “educational” services, but J&J's website states that the company paid him \$32,017 for consulting, promotional talks, meals, and travel that year.

438. Dr. Fine and Dr. Portenoy co-wrote *A Clinical Guide to Opioid Analgesia*, in which they downplayed the risks of opioid treatment, such as respiratory depression and addiction:

At clinically appropriate doses ... respiratory rate typically does not decline. Tolerance to the respiratory effects usually develops quickly, and doses can be steadily increased without risk.

Overall, the literature provides evidence that the outcomes of drug abuse and addiction are rare among patients who receive opioids for a short period (i.e., for acute pain) and among those with no history of abuse who receive long-term therapy for medical indications.

439. In November 2010, Dr. Fine and others published an article presenting the results of another Cephalon-sponsored study titled “Long-Term Safety and Tolerability of Fentanyl Buccal Tablet for the Treatment of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Pain: An 18-Month Study.” In that article, Dr. Fine explained that the 18-month “open-label” study “assessed the safety and tolerability of FBT [Fentora] for the [long-term] treatment of BTP in a large cohort . . . of opioid-tolerant patients receiving around-the-clock . . . opioids for noncancer pain.” The article acknowledged that: (a) “[t]here has been a steady increase in the use of opioids for the management of chronic noncancer pain over the past two decades”; (b) the “widespread acceptance” had led to the publishing of practice guidelines “to provide evidence- and consensus-based recommendations for the optimal use of opioids in the management of chronic pain”; and (c) those guidelines lacked “data assessing the long-term benefits and harms of opioid therapy for chronic pain.”

440. The article concluded: “[T]he safety and tolerability profile of FBT in this study was generally typical of a potent opioid. The [adverse events] observed were, in most cases, predictable, manageable, and tolerable.” They also conclude that the number of abuse-related events was “small.”

441. Multiple videos feature Dr. Fine delivering educational talks about the drugs. In one video from 2011 titled “Optimizing Opioid Therapy,” he sets forth a “Guideline for Chronic Opioid Therapy” discussing “opioid rotation” (switching from one opioid to another) not only for cancer patients, but for non-cancer patients, and suggests it may take four or five switches over a person’s “lifetime” to manage pain. He states the “goal is to improve effectiveness which is different from efficacy and safety.” Rather, for chronic pain patients, effectiveness “is a balance of therapeutic good and adverse events *over the course of years*.” The entire program assumes that

opioids are appropriate treatment over a “protracted period of time” and even over a patient’s entire “lifetime.” He even suggests that opioids can be used to treat *sleep apnea*. He further states that the associated risks of addiction and abuse can be managed by doctors and evaluated with “tools,” but leaves that for “a whole other lecture.”

d. Dr. Fishman

442. Dr. Fishman is a physician whose ties to the opioid drug industry are prolific. He has served as an APF board member and as president of the AAPM and has participated tirelessly in numerous annual CME activities for which he received “market rate honoraria.” As discussed below, he has authored publications, including the seminal guides on opioid prescribing, which were funded by the Manufacturer Defendants. He has also worked to oppose legislation requiring doctors and others to consult pain specialists before prescribing high doses of opioids to non-cancer patients. He has acknowledged his failure to disclose all potential conflicts of interest in a letter in the *Journal of the American Medical Association* titled “Incomplete Financial Disclosures in a Letter on Reducing Opioid Abuse and Diversion.”

443. Dr. Fishman authored a physician’s guide on the use of opioids to treat chronic pain titled “Responsible Opioid Prescribing,” in 2007 which promoted the notion that long-term opioid treatment was a viable and safe option for treating chronic pain.

444. In 2012, Dr. Fishman updated the guide and continued emphasizing the “catastrophic” “under-treatment” of pain and the “crisis” such under-treatment created:

Given the magnitude of the problems related to opioid analgesics, it can be tempting to resort to draconian solutions: clinicians may simply stop prescribing opioids, or legislation intended to improve pharmacovigilance may inadvertently curtail patient access to care. As we work to reduce diversion and misuse of prescription opioids, it’s critical to remember that the problem of unrelieved pain remains as urgent as ever.

445. The updated guide still assures that “[o]pioid therapy to relieve pain and improve function is legitimate medical practice for acute and chronic pain of both cancer and noncancer origins.”

446. In another guide by Dr. Fishman, he continues to downplay the risk of addiction: “I believe clinicians must be very careful with the label ‘addict.’ I draw a distinction between a ‘chemical coper’ and an addict.” The guide also continues to present symptoms of addiction as symptoms of “pseudoaddiction.”

3. *The Manufacturer Defendants Disseminated Their Misrepresentations Through Continuing Medical Education*

447. Once the Manufacturer Defendants had assembled a group of physician promoters and built a false body of “literature,” they needed to make sure their false marketing message was widely distributed. One way the Manufacturer Defendants did so was through CMEs.

448. A CME is a professional education program provided to doctors. Doctors are required to attend a certain number and, often, type of CME programs each year as a condition of their licensure. These programs are delivered in person, often in connection with professional organizations’ conferences, online, and through written publications. Doctors rely on CMEs not only to satisfy licensing requirements but also to get information on new developments in medicine or to deepen their knowledge in specific areas of practice. Because CMEs typically are taught by KOLs who are highly respected in their fields and are thought to reflect these physicians’ medical expertise, they can be especially influential with doctors.

449. The countless doctors and other health care professionals who participate in accredited CMEs constitute an enormously important audience for opioid reeducation. As one target, Defendants aimed to reach general practitioners, whose broad area of practice and lack of

expertise and specialized training in pain management made them particularly dependent upon CMEs and, as a result, especially susceptible to the Manufacturer Defendants' deceptions.

450. The Manufacturer Defendants sponsored CMEs that were delivered thousands of times, promoting chronic opioid therapy and supporting and disseminating the deceptive and biased messages described in this Complaint. These CMEs, while often generically titled to relate to the treatment of chronic pain, focus on opioids to the exclusion of alternative treatments, inflate the benefits of opioids, and frequently omit or downplay their risks and adverse effects.

451. Cephalon sponsored numerous CME programs, which were made widely available through organizations like Medscape, LLC ("Medscape") and which disseminated false and misleading information to physicians across the country.

452. Another Cephalon-sponsored CME presentation titled *Breakthrough Pain: Treatment Rationale with Opioids* was available on Medscape starting September 16, 2003, and was given by a self-professed pain management doctor who "previously operated back, complex pain syndromes, the neuropathies, and interstitial cystitis." He describes the pain process as a non-time-dependent continuum that requires a balanced analgesia approach using "targeted pharmacotherapeutics to affect multiple points in the pain-signaling pathway." The doctor lists fentanyl as one of the most effective opioids available for treating breakthrough pain, describing its use as an expected and normal part of the pain management process. Nowhere in the CME is cancer or cancer-related pain even mentioned, despite FDA restrictions that fentanyl use be limited to cancer-related pain.

453. Teva paid to have a CME it sponsored, *Opioid-Based Management of Persistent and Breakthrough Pain*, published in a supplement of Pain Medicine News in 2009. The CME instructed doctors that "clinically, broad classification of pain syndromes as either cancer- or

noncancer-related has limited utility” and recommended Actiq and Fentora for patients with chronic pain. The CME is still available online.

454. *Responsible Opioid Prescribing* was sponsored by Purdue, Endo, and Teva. The FSMB website described it as the “leading continuing medical education (CME) activity for prescribers of opioid medications.” Endo sales representatives distributed copies of *Responsible Opioid Prescribing* with a special introductory letter from Dr. Fishman.

455. In all, more than 163,000 copies of *Responsible Opioid Prescribing* were distributed nationally.

456. The American Medical Association (“AMA”) recognized the impropriety that pharmaceutical company-funded CMEs creates; stating that support from drug companies with a financial interest in the content being promoted “creates conditions in which external interests could influence the availability and/or content” of the programs and urges that “[w]hen possible, CME[s] should be provided without such support or the participation of individuals who have financial interests in the education subject matter.”

457. Physicians attended or reviewed CMEs sponsored by the Manufacturer Defendants during the relevant time period and were misled by them.

458. By sponsoring CME programs put on by Front Groups like APF, AAPM, and others, the Manufacturer Defendants could expect instructors to deliver messages favorable to them, as these organizations were dependent on the Manufacturer Defendants for other projects. The sponsoring organizations honored this principle by hiring pro-opioid KOLs to give talks that supported chronic opioid therapy. Manufacturer Defendant-driven content in these CMEs had a direct and immediate effect on prescribers’ views on opioids. Producers of CMEs and the Manufacturer Defendants both measure the effects of CMEs on prescribers’ views on opioids and

their absorption of specific messages, confirming the strategic marketing purpose in supporting them.

4. *The Manufacturer Defendants Used “Branded” Advertising to Promote their Products to Doctors and Consumers*

459. The Manufacturer Defendants engaged in widespread advertising campaigns touting the benefits of their branded drugs. The Manufacturer Defendants published print advertisements in a broad array of medical journals, ranging from those aimed at specialists, such as the *Journal of Pain* and *Clinical Journal of Pain*, to journals with wider medical audiences, such as the *Journal of the American Medical Association*. The Manufacturer Defendants collectively spent more than \$14 million on the medical journal advertising of opioids in 2011, nearly triple what they spent in 2001. The 2011 total includes \$8.3 million by Purdue, \$4.9 million by Janssen, and \$1.1 million by Endo.

460. The Manufacturer Defendants also targeted consumers in their advertising. They knew that physicians are more likely to prescribe a drug if a patient specifically requests it. They also knew that this willingness to acquiesce to such patient requests holds true even for opioids and for conditions for which they are not approved. Endo’s research, for example, also found that such communications resulted in greater patient “brand loyalty,” with longer durations of Opana ER therapy and fewer discontinuations. The Manufacturer Defendants thus increasingly took their opioid sales campaigns directly to consumers, including through patient-focused “education and support” materials in the form of pamphlets, videos, or other publications that patients could view in their physician’s office.

5. *The Manufacturer Defendants Used “Unbranded” Advertising To Promote Opioid Use For Chronic Pain Without FDA Review*

461. The Manufacturer Defendants also aggressively promoted opioids through “unbranded advertising” to generally tout the benefits of opioids without specifically naming a

particular brand-name opioid drug. Instead, unbranded advertising is usually framed as “disease awareness”—encouraging consumers to “talk to your doctor” about a certain health condition without promoting a specific product and, therefore, without providing balanced disclosures about the product’s limits and risks. In contrast, a pharmaceutical company’s “branded” advertisement that identifies a specific medication and its indication (i.e., the condition which the drug is approved to treat) must also include possible side effects and contraindications—what the FDA Guidance on pharmaceutical advertising refers to as “fair balance.” Branded advertising is also subject to FDA review for consistency with the drug’s FDA-approved label. Through unbranded materials, the Manufacturer Defendants expanded the overall acceptance of and demand for chronic opioid therapy without the restrictions imposed by regulations on branded advertising.

462. Many of the Manufacturer Defendants utilized unbranded websites to promote opioid use without promoting a specific branded drug, such as Purdue’s pain-management website, www.inthefaceofpain.com. The website contained testimonials from several dozen “advocates,” including health care providers, urging more pain treatment. The website presented the advocates as neutral and unbiased, but an investigation by the New York Attorney General later revealed that Purdue paid the advocates hundreds of thousands of dollars.

6. *The Manufacturer Defendants Funded, Edited and Distributed Publications That Supported Their Misrepresentations*

463. The Manufacturer Defendants created a body of false, misleading, and unsupported medical and popular literature about opioids that (a) understated the risks and overstated the benefits of long-term use; (b) appeared to be the result of independent, objective research; and (c) was likely to shape the perceptions of prescribers, patients, and payors. This literature served marketing goals, rather than scientific standards, and was intended to persuade doctors and consumers that the benefits of long-term opioid use outweighed the risks.

464. To accomplish their goal, the Manufacturer Defendants—sometimes through third-party consultants and/or Front Groups—commissioned, edited, and arranged for the placement of favorable articles in academic journals.

465. The Manufacturer Defendants' plans for these materials did not originate in the departments with the organizations that were responsible for research, development, or any other area that would have specialized knowledge about the drugs and their effects on patients; rather, they originated in the Manufacturer Defendants' marketing departments.

466. The Manufacturer Defendants made sure that favorable articles were disseminated and cited widely in the medical literature, even when the Manufacturer Defendants knew that the articles distorted the significance or meaning of the underlying study, as with the Porter & Jick letter. The Manufacturer Defendants also frequently relied on unpublished data or posters, neither of which are subject to peer review, but were presented as valid scientific evidence.

467. The Manufacturer Defendants published or commissioned deceptive review articles, letters to the editor, commentaries, case-study reports, and newsletters aimed at discrediting or suppressing negative information that contradicted their claims or raised concerns about chronic opioid therapy.

468. For example, in 2007 Cephalon sponsored the publication of an article titled "Impact of Breakthrough Pain on Quality of Life in Patients with Chronic, Noncancer Pain: Patient Perceptions and Effect of Treatment with Oral Transmucosal Fentanyl Citrate," published in the nationally circulated journal *Pain Medicine*, to support its effort to expand the use of its branded fentanyl products. The article's authors (including Dr. Webster) stated that the "OTFC [fentanyl] has been shown to relieve BTP more rapidly than conventional oral, normal-release, or 'short-acting' opioids" and that "[t]he purpose of [the] study was to provide a qualitative evaluation of

the effect of BTP on the [quality of life] of noncancer pain patients.” The number-one-diagnosed cause of chronic pain in the patients studied was back pain (44%), followed by musculoskeletal pain (12%) and head pain (7%). The article cites Dr. Portenoy and recommends fentanyl for non-cancer BTP patients:

In summary, BTP appears to be a clinically important condition in patients with chronic noncancer pain and is associated with an adverse impact on QoL. This qualitative study on the negative impact of BTP and the potential benefits of BTP-specific therapy suggests several domains that may be helpful in developing BTP-specific, QoL assessment tools.

7. *The Manufacturer Defendants Used Sales Representatives to Directly Disseminate Their Misrepresentations to Prescribers*

469. The Manufacturer Defendants’ sales representatives executed carefully crafted marketing tactics, developed at the highest rungs of their corporate ladders, to reach targeted doctors with centrally orchestrated messages. The Manufacturer Defendants’ sales representatives also distributed third-party marketing material to their target audience that was deceptive.

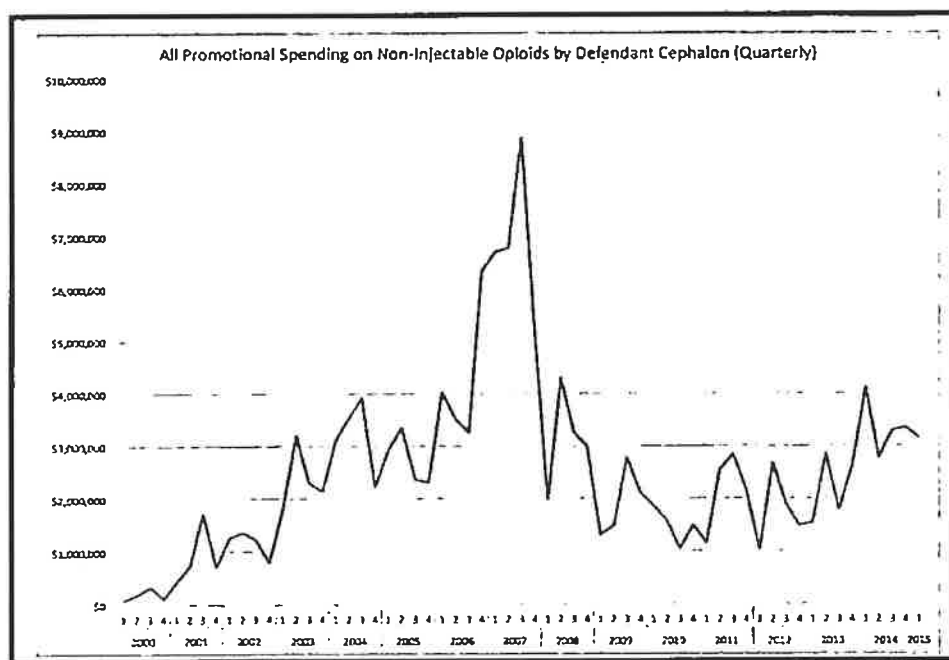
470. Each Manufacturer Defendant promoted opioids through sales representatives (also called “detailers”) and, upon information and belief, small group speaker programs to reach out to individual prescribers. By establishing close relationships with doctors, the Manufacturer Defendants were able to disseminate their misrepresentations in targeted, one-on-one settings that allowed them to promote their opioids and to allay individual prescribers’ concerns about prescribing opioids for chronic pain.

471. In accordance with common industry practice, the Manufacturer Defendants purchase and closely analyze prescription sales data from IMS Health (now IQVIA), a healthcare data collection, management, and analytics corporation. This data allows them to track precisely the rates of initial and renewal prescribing by individual doctors, which allows them to target and

tailor their appeals. Sales representatives visited hundreds of thousands of doctors and disseminated the misinformation and materials described above.

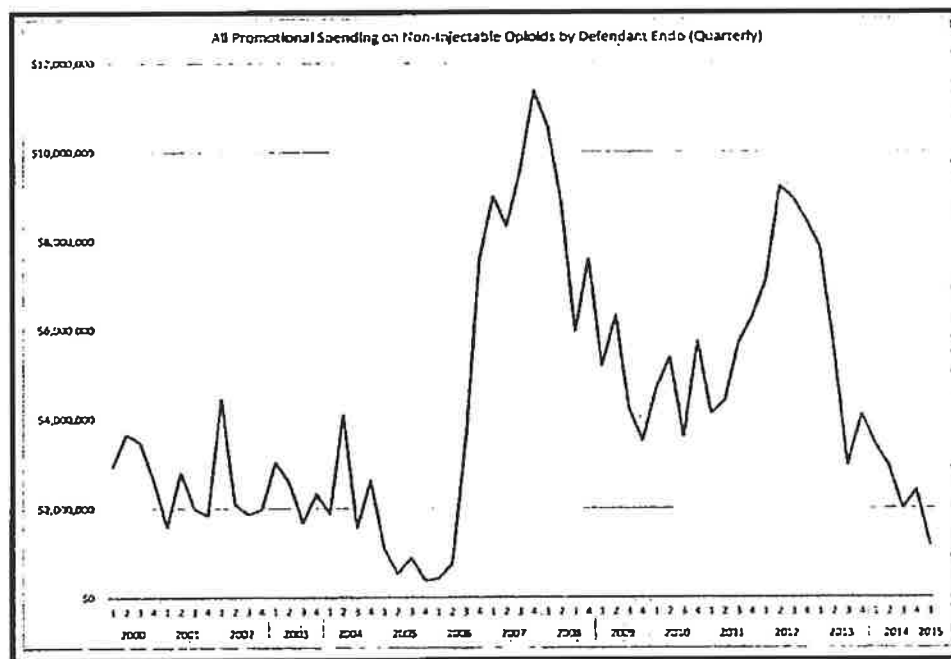
472. Manufacturer Defendants devoted and continue to devote massive resources to direct sales contacts with doctors. In 2014 alone, Manufacturer Defendants spent \$166 million on detailing branded opioids to doctors. This amount is twice as much as Manufacturer Defendants spent on detailing in 2000. The amount includes \$108 million spent by Purdue, \$34 million by Janssen, \$13 million by Teva, and \$10 million by Endo.

473. Cephalon's quarterly spending steadily climbed from below \$1 million in 2000 to more than \$3 million in 2014 (and more than \$13 million for the year), with a peak, coinciding with the launch of Fentora, of more than \$27 million in 2007, as shown below:

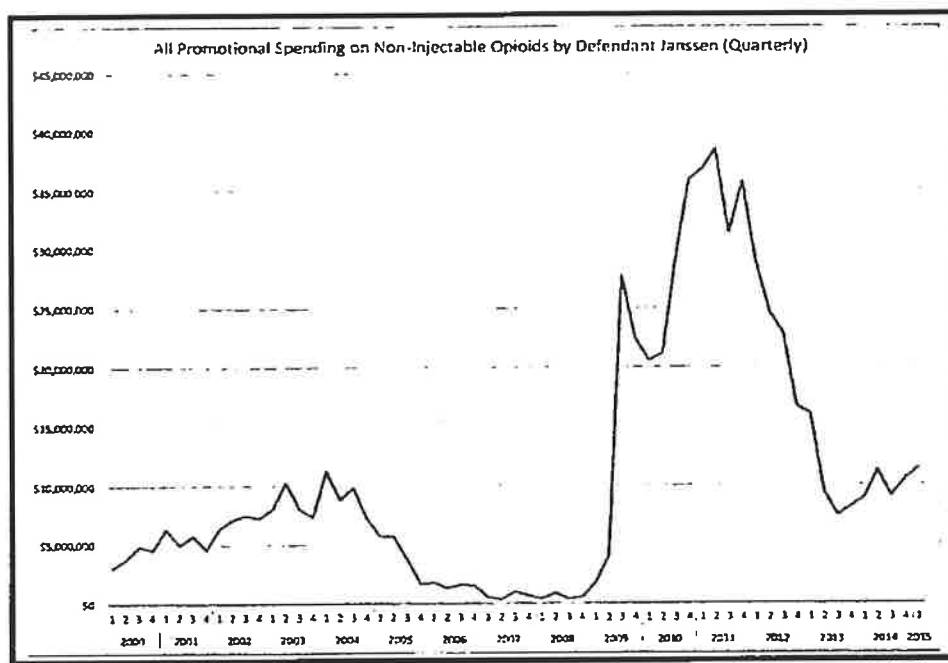


474. Endo's quarterly spending went from the \$2 million to \$4 million range in 2000-2004 to more than \$10 million following the launch of Opana ER in mid-2006 (and more than \$38

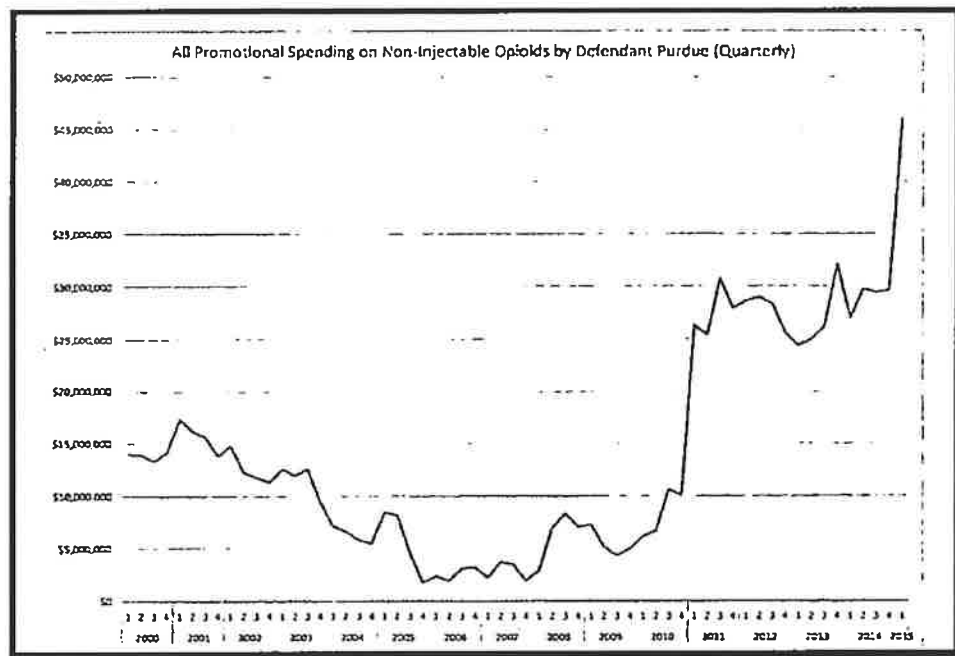
million for the year in 2007) and more than \$8 million coinciding with the launch of a reformulated version in 2012 (and nearly \$34 million for the year):



475. Janssen's quarterly spending dramatically rose from less than \$5 million in 2000 to more than \$30 million in 2011, coinciding with the launch of Nucynta ER (with yearly spending at \$142 million for 2011), as shown below:



476. Purdue's quarterly spending notably decreased from 2000 to 2007—as Purdue came under investigation by the Department of Justice—but, as shown in the chart below, its spending increased dramatically after it settled with the DOJ in 2007, pleaded guilty to misleading doctors and patients about opioids, and paid a fine:



477. For its opioid, Actiq, Cephalon also engaged in direct marketing in direct contravention of the FDA's strict instructions that Actiq be prescribed only to terminal cancer patients and by oncologists and pain management doctors experienced in treating cancer pain.

478. Thousands of prescribers attended Cephalon speaking programs.

8. Manufacturer Defendants Used Speakers' Bureaus and Programs to Spread Their Deceptive Messages

479. In addition to making sales calls, Manufacturer Defendants' sales representatives also identified doctors to serve, for payment, on their speakers' bureaus and to attend programs with speakers and meals paid for by the Manufacturer Defendants. These speaker programs and associated speaker trainings serve three purposes: they provide an incentive to doctors to prescribe or increase their prescriptions of, a particular drug; to qualify to be selected a forum in which to further market to the speaker himself or herself; and an opportunity to market to the speaker's peers. The Manufacturer Defendants grade their speakers, and future opportunities are based on speaking performance, post-program sales, and product usage. Purdue, Janssen, Endo, Cephalon,

and Mallinckrodt each made thousands of payments to physicians nationwide, for activities including participating in speakers' bureaus, providing consulting services, and other services.

480. As detailed below, Insys paid prescribers for *fake* speakers' programs in exchange for prescribing its product, Subsys. Insys's schemes resulted in countless speakers' programs at which the designated speaker did not speak, and, on many occasions, speaker programs at which the only attendees at the events were the speaker and an Insys sales representative. It was a pay-to-prescribe program.

481. Insys used speakers' programs as a front to pay for prescriptions and paid to push opioids onto patients who did not need them.

C. The Manufacturer Defendants Targeted Vulnerable Populations

482. The Manufacturer Defendants specifically targeted their marketing at two vulnerable populations—the elderly and veterans.

483. Elderly patients taking opioids have been found to be exposed to elevated fracture risks, a greater risk for hospitalizations, and increased vulnerability to adverse drug effects and interactions, such as respiratory depression which occurs more frequently in elderly patients.

484. The Manufacturer Defendants promoted the notion—without adequate scientific foundation—that the elderly are particularly unlikely to become addicted to opioids. The AGS 2009 Guidelines, for example, which Purdue, Endo, and Janssen publicized, described the risk of addiction as “*exceedingly low* in older patients with no current or past history of substance abuse.” (emphasis added). As another example, an Endo-sponsored CME put on by NIPC, *Persistent Pain in the Older Adult*, taught that prescribing opioids to older patients carried “possibly less potential for abuse than in younger patients.” Contrary to these assertions, however, a 2010 study examining overdoses among long-term opioid users found that patients 65 or older were among those with the largest number of serious overdoses.

485. Similarly, Endo targeted marketing of Opana ER towards patients over 55 years old. Such documents show Endo treated Medicare part D patients among the “most valuable customer segments.” However, in 2013, one pharmaceutical benefits management company recommended against the use of Opana ER for elderly patients and unequivocally concluded: “[f]or patients 65 and older these medications are not safe, so consult your doctor.”

486. According to a study published in the 2013 *Journal of American Medicine*, veterans returning from Iraq and Afghanistan who were prescribed opioids have a higher incidence of adverse clinical outcomes, such as overdoses and self-inflicted and accidental injuries. A 2008 survey showed that prescription drug misuse among military personnel doubled from 2002 to 2005, and then nearly tripled again over the next three years. Veterans are twice as likely as non-veterans to die from an opioid overdose.

487. Yet the Manufacturer Defendants deliberately targeted veterans with deceptive marketing. For example, a 2009 publication sponsored by Purdue, Endo, and Janssen, and distributed by APF with grants from Janssen and Endo, was written as a personal narrative of one veteran but was, in fact, another vehicle for opioid promotion. Called *Exit Wounds*, the publication describes opioids as “underused” and the “gold standard of pain medications” while failing to disclose significant risks of opioid use, including the risks of fatal interactions with benzodiazepines. According to a VA Office of Inspector General Report, 92.6% of veterans who were prescribed opioid drugs were also prescribed benzodiazepines, despite the increased danger of respiratory depression from the two drugs together.

488. Opioid prescriptions have dramatically increased for veterans and the elderly. Since 2007, prescriptions for the elderly have grown at twice the rate of prescriptions for adults

between the ages of 40 and 59. And in 2009, military doctors wrote 3.8 million prescriptions for narcotic pain pills—four times as many as they did in 2001.

D. Insys Employed Fraudulent, Illegal, and Misleading Marketing Schemes to Promote Subsys

489. Insys's opioid, Subsys, was approved by the FDA in 2012 for "management of breakthrough pain in adult cancer patients who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain." Under FDA rules, Insys could only market Subsys for this use. Subsys consists of the highly addictive narcotic, fentanyl, administered via a sublingual (under the tongue) spray, which provides rapid-onset pain relief. It is in the class of drugs described as Transmucosal Immediate-Release Fentanyl ("TIRF").

490. To reduce the risk of abuse, misuse, and diversion, the FDA instituted a Risk Evaluation and Mitigation Strategy ("REMS") for Subsys and other TIRF products, such as Cephalon's Actiq and Fentora. The purpose of REMS was to educate "prescribers, pharmacists, and patients on the potential for misuse, abuse, addiction, and overdose" for this type of drug and to "ensure safe use and access to these drugs for patients who need them." Prescribers must enroll in the TIRF REMS before writing a prescription for Subsys.

491. Since its launch, Subsys has been an extremely expensive medication, and its price continues to rise each year. Depending on a patient's dose strength and frequency of use, a month's supply of Subsys could cost in the thousands of dollars.

492. Due to its high cost, in most instances, prescribers must submit Subsys prescriptions to insurance companies or health benefit payors for prior authorization to determine whether they will pay for the drug prior to the patient attempting to fill the prescription. According to the U.S. Senate Homeland Security and Governmental Affairs Committee Minority Staff Report ("Staff Report"), the prior authorization process includes "confirmation that the patient had an active

cancer diagnosis, was being treated by an opioid (and, thus, was opioid tolerant), and was being prescribed Subsys to treat breakthrough pain that the other opioid could not eliminate. If any one of these factors was not present, the prior authorization would be denied”

493. These prior authorization requirements proved to be daunting. Subsys received reimbursement approval in only approximately 30% of submitted claims. In order to increase approvals, Insys created a prior authorization unit, called the Insys Reimbursement Center (“IRC”), to obtain approval for Subsys reimbursements. This unit employed a number of fraudulent and misleading tactics to secure reimbursements, including falsifying medical histories of patients, falsely claiming that patients had cancer, and providing misleading information to insurers and payors regarding patients’ diagnoses and medical conditions.

494. Subsys has proved to be extremely profitable for Insys. Insys made approximately \$330 million in net revenue from Subsys last year. Between 2013 and 2016, the value of Insys stock rose 296%.

495. Since its launch in 2012, Insys aggressively worked to grow its profits through fraudulent, illegal, and misleading tactics, including its reimbursement-related fraud. Through its sales representatives and other marketing efforts, Insys deceptively promoted Subsys as safe and appropriate for uses such as treating neck and back pain without disclosing the lack of approval or evidence for such uses and misrepresented the appropriateness of Subsys for treating those conditions. It implemented a kickback scheme wherein it paid prescribers for fake speakers’ programs in exchange for prescribing Subsys. All of these fraudulent and misleading schemes had the effect of pushing Insys’s dangerous opioid onto patients who did not need it.

496. Insys incentivized its sales force to engage in illegal and fraudulent conduct. Many of the Insys sales representatives were new to the pharmaceutical industry and their base salaries

were low compared to industry standard. The compensation structure was heavily weighted toward commissions and rewarded reps more for selling higher (and more expensive) doses of Subsys, a “highly unusual” practice because most companies consider dosing a patient-specific decision that should be made by a doctor.

497. The Insys “speakers program” was perhaps its most widespread and damaging scheme. A former Insys salesman, Ray Furchak, alleged in a *qui tam* action that the sole purpose of the speakers program was “in the words of his then supervisor Alec Burlakoff, ‘to get money in the doctor’s pocket.’” Furchak went on to explain that “[t]he catch ... was that doctors who increased the level of Subsys prescriptions, and at higher dosages (such as 400 or 800 micrograms instead of 200 micrograms), would receive the invitations to the program—and the checks.” It was a pay-to-prescribe program.

498. Insys’s sham speaker program and other fraudulent and illegal tactics have been outlined in great detail in indictments and guilty pleas of Insys executives, employees, and prescribers across the country, as well as in a number of lawsuits against the company itself.

499. In May of 2015, two Alabama pain specialists were arrested and charged with illegal prescription drug distribution, among other charges. The doctors were the top prescribers of Subsys, though neither were oncologists. According to prosecutors, the doctors received illegal kickbacks from Insys for prescribing Subsys. Both doctors had prescribed Subsys to treat neck, back, and joint pain. In February of 2016, a former Insys sales manager pled guilty to conspiracy to commit health care fraud, including engaging in a kickback scheme in order to induce one of these doctors to prescribe Subsys. The plea agreement states that nearly all of the Subsys prescriptions written by the doctor were off-label to non-cancer patients. In May of 2017, one of the two doctors was sentenced to 20 years in prison.

500. In June of 2015, a nurse practitioner in Connecticut described as the state's highest Medicare prescriber of narcotics, pled guilty to receiving \$83,000 in kickbacks from Insys for prescribing Subsys. Most of her patients were prescribed the drug for chronic pain. Insys paid the nurse as a speaker for more than 70 dinner programs at approximately \$1,000 per event; however, she did not give any presentations. In her guilty plea, the nurse admitted receiving the speaker fees in exchange for writing prescriptions for Subsys.

501. In August of 2015, Insys settled a complaint brought by the Oregon Attorney General. In its complaint, the Oregon Department of Justice cited Insys for, among other things, misrepresenting to doctors that Subsys could be used to treat migraine, neck pain, back pain, and other uses for which Subsys is neither safe nor effective, and using speaking fees as kickbacks to incentivize doctors to prescribe Subsys.

502. In August of 2016, the State of Illinois sued Insys for similar deceptive and illegal practices. The Complaint alleged that Insys marketed Subsys to high-volume prescribers of opioid drugs instead of to oncologists whose patients experienced the breakthrough cancer pain for which the drug is indicated. The Illinois Complaint also details how Insys used its speaker program to pay high volume prescribers to prescribe Subsys. The speaker events took place at upscale restaurants in the Chicago area, and Illinois speakers received an "honorarium" ranging from \$700 to \$5,100, and they were allowed to order as much food and alcohol as they wanted. At most of the events, the "speaker" being paid by Insys did not speak, and, on many occasions, the only attendees at the events were the speaker and an Insys sales representative.

503. In December of 2016, six Insys executives and managers were indicted and then, in October 2017, Insys's founder and the owner was arrested and charged with multiple felonies in connection with an alleged conspiracy to bribe practitioners to prescribe Subsys and defraud

insurance companies. A U.S. Department of Justice press release explained that among other things: “Insys executives improperly influenced health care providers to prescribe a powerful opioid for patients who did not need it, and without complying with FDA requirements, thus putting patients at risk and contributing to the current opioid crisis.” A Drug Enforcement Administration (“DEA”) Special Agent in Charge further explained that: “Pharmaceutical companies whose products include controlled medications that can lead to addiction and overdose have a special obligation to operate in a trustworthy, transparent manner because their customers’ health and safety and, indeed, very lives depend on it.”

E. The Manufacturer Defendants’ Scheme Succeeded, Creating a Public Health Epidemic

1. The Manufacturer Defendants dramatically expanded opioid prescribing and use

504. The Manufacturer Defendants necessarily expected a return on the enormous investment they made in their deceptive marketing scheme and worked to measure and expand their success. Their own documents show that they knew they were influencing prescribers and increasing prescriptions. Studies also show that in doing so, they fueled an epidemic of addiction and abuse.

505. Endo, for example, directed the majority of its marketing budget to sales representatives—with good results: 84% of its prescriptions were from the doctors they detailed. Moreover, as of 2008, cancer and post-operative pain accounted for only 10% of Opana ER’s uses; virtually all of Endo’s opioid sales—and profits—were from a market that did not exist ten years earlier. Internal emails from Endo staff attributed increases in Opana ER sales to the aggressiveness and persistence of sales representatives.

506. Cephalon also recognized the return of its efforts to market Actiq and Fentora off-label for chronic pain. In 2000, Actiq generated \$15 million in sales. By 2002, Actiq sales had

increased by 92%, which Cephalon attributed to “a dedicated sales force for ACTIQ” and “ongoing changes to [its] marketing approach including hiring additional sales representatives and targeting our marketing efforts to pain specialists.” Actiq became Cephalon’s second best-selling drug. By the end of 2006, Actiq’s sales had exceeded \$500 million. Only 1% of the 187,076 prescriptions for Actiq filled at retail pharmacies during the first six months of 2006 were prescribed by oncologists. One measure suggested that “more than 80 percent of patients who use[d] the drug don’t have cancer.”

507. Upon information and belief, each of the Manufacturer Defendants tracked the impact of their marketing efforts to measure their impact in changing doctors’ perceptions and prescribing their drugs. They purchased prescribing and survey data that allowed them to closely monitor these trends, and they did actively monitor them. For instance, they monitored doctors’ prescribing before and after detailing visits, and at various levels of detailing intensity, and before and after speaker programs. Defendants invested in their aggressive and deceptive marketing for one reason: it worked. As described in this Complaint, both in specific instances and more generally, Defendants’ marketing changed prescribers’ willingness to prescribe opioids, led them to prescribe more of their opioids, and persuaded them to continue prescribing opioids or to switch to supposedly “safer” opioids, such as ADF.

508. This success would have come as no surprise. Drug company marketing materially impacts doctors’ prescribing behavior. The effects of sales calls on prescribers’ behavior is well documented in the literature, including a 2017 study that found that physicians ordered fewer promoted brand-name medications and prescribed more cost-effective generic versions if they worked in hospitals that instituted rules about when and how pharmaceutical sales representatives were allowed to detail prescribers. The changes in prescribing behavior appeared strongest at

hospitals that implemented the strictest detailing policies and included enforcement measures. Another study examined four practices, including visits by sales representatives, medical journal advertisements, direct-to-consumer advertising, and pricing, and found that sales representatives have the strongest effect on drug utilization. An additional study found that doctor meetings with sales representatives are related to changes in both prescribing practices and requests by physicians to add the drugs to hospitals' formularies.

509. Manufacturer Defendants spent millions of dollars to market their drugs to prescribers and patients and meticulously tracked their return on that investment. In one recent survey published by the AMA, even though nine in ten general practitioners reported prescription drug abuse to be a moderate to large problem in their communities, 88% of the respondents said they were confident in their prescribing skills, and nearly half were comfortable using opioids for chronic non-cancer pain. These results are directly due to the Manufacturer Defendants' fraudulent marketing campaign focused on several misrepresentations.

510. Thus, both independent studies and Manufacturer Defendants' own behavior confirm that Defendants' marketing scheme dramatically increased their sales.

2. *Manufacturer Defendants' deception in expanding their market created and fueled the opioid epidemic*

511. Independent research demonstrates a close link between opioid prescriptions and opioid abuse. For example, a 2007 study found "a very strong correlation between therapeutic exposure to opioid analgesics, as measured by prescriptions filled, and their abuse." It has been estimated that 60% of the opioids that are abused come, directly or indirectly, through physicians' prescriptions.

512. There is a parallel relationship between the availability of prescription opioid analgesics through legitimate pharmacy channels and the diversion and abuse of these drugs and

associated adverse outcomes. The opioid epidemic is “directly related to the increasingly widespread misuse of powerful opioid pain medications.”

513. In a 2016 report, the CDC explained that “[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses.” Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical “to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity.”

V. DEFENDANTS THROUGHOUT THE SUPPLY CHAIN DELIBERATELY DISREGARDED THEIR DUTIES TO MAINTAIN EFFECTIVE CONTROLS AND TO IDENTIFY, REPORT, AND TAKE STEPS TO HALT SUSPICIOUS ORDERS

514. The Manufacturer Defendants created a vastly and dangerously larger market for opioids. They and the Distributor Defendants compounded this harm by facilitating the supply of far more opioids that could have been justified to serve that market. The failure of the Defendants to maintain effective controls, and to investigate, report, and take steps to halt orders that they knew or should have known were suspicious breached both their statutory and common law duties.

515. Manufacturer Defendants’ scheme was resoundingly successful. Chronic opioid therapy—the prescribing of opioids long-term to treat chronic pain—has become a commonplace, and often first-line, treatment. Manufacturing Defendants’ deceptive marketing caused prescribing not only of their opioids but of opioids as a class, to skyrocket. According to the CDC opioid prescriptions, as measured by the number of prescriptions and morphine milligram equivalent (“MME”) per person, tripled from 1999 to 2015. In 2015, on an average day, more than 650,000 opioid prescriptions were dispensed in the U.S. While previously a small minority of opioid sales, today between 80% and 90% of opioids (measured by weight) used are for chronic pain. Approximately 20% of the population between the ages of 30 and 44, and nearly 30% of the

population over 45, have used opioids. Opioids are the most common treatment for chronic pain, and 20% of office visits now include the prescription of an opioid.

516. In a 2016 report, the CDC explained that “[o]pioid pain reliever prescribing has quadrupled since 1999 and has increased in parallel with [opioid] overdoses.” Patients receiving opioid prescriptions for chronic pain account for the majority of overdoses. For these reasons, the CDC concluded that efforts to rein in the prescribing of opioids for chronic pain are critical “to reverse the epidemic of opioid drug overdose deaths and prevent opioid-related morbidity.”

517. As the Manufacturer Defendants increased the demand for opioids, all the Defendants aggressively sought to bolster their revenue, increase profit, and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, Defendants are not permitted to engage in a limitless expansion of their sales through the unlawful sales of regulated painkillers. Rather, as described below, Defendants are subject to various duties to report the quantity of Schedule II controlled substances in order to monitor such substances and prevent oversupply and diversion into the illicit market.

A. Manufacturer Defendants and Distributor Defendants Have a Duty to Report Suspicious Orders and Not to Ship Those Orders Unless Due Diligence Disproves Their Suspicions

518. Multiple sources impose duties on the Defendants to report suspicious orders and further to not ship those orders unless due diligence disproves those suspicions.

519. First, under the common law, the Defendants had a duty to exercise reasonable care in delivering dangerous narcotic substances. By flooding the market, including Plaintiff’s Community, with more opioids than could be used for legitimate medical purposes and by filling and failing to report orders that they knew or should have realized were likely being diverted for illicit uses, Defendants breached that aforementioned duty by intentionally creating and failing to prevent a foreseeable risk of harm.

520. Second, each of the Defendants assumed a duty, when speaking publicly about opioids and their efforts to combat diversion, to speak accurately and truthfully.

521. Third, each of the Manufacturer Defendants and Distributor Defendants was required to register with the DEA to manufacture and/or distribute Schedule II controlled substances. *See* 21 U.S.C. § 823(a)-(b), (e); 28 C.F.R. § 0.100. As registrants, these Defendants were required to “maint[ain] ... effective controls against diversion” and to “design and operate a system to disclose ... suspicious orders of controlled substances.” 21 U.S.C. § 823(a)-(b); 21 C.F.R. § 1301.74. These Defendants were further required to take steps to halt suspicious orders. These Defendants violated their obligations under federal law.

522. Fourth, Defendants also breached duties under Pennsylvania law. The Distributor Defendants operate within Pennsylvania and Bedford County distributing prescription opioid drugs to pharmacies and other health care providers. As a result, the Pennsylvania Wholesale Prescription Drug Distributors License Act (WPDDLA) requires the Distributor Defendants to register with and meet the licensing requirements of the Pennsylvania Department of Health. 63 P.S. § 391.3. The Pennsylvania Controlled Substance, Drug, Device, and Cosmetic Act (PCSA), 35 P.S. § 780, et seq., also requires Distributor Defendants to register as distributors of controlled substances with the Commonwealth’s Secretary of Health. 35 P.S. § 780-106.

523. At all relevant times, the Distributor Defendants purchased prescription opioid drugs from manufacturers and sold them to pharmacies and other health care providers in Pennsylvania and Bedford County.

524. The Distributor Defendants dominate 85% of the market share for the distribution of prescription opioids. On information and belief, most or nearly all of the prescription opioids

that were sold to health care providers within Pennsylvania and Bedford County were purchased from the Distributor Defendants.

525. The PSCA tracks and incorporates federal regulations that require the Distributor Defendants to “design and operate a system to disclose . . . suspicious orders of controlled substances . . . Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.” 35 P.S. § 780-112(c) (incorporating 21 C.F.R. § 1301.74(b)).

526. Under the relevant Pennsylvania statutes, the PSCA and WPDDLA, the Distributor Defendants are required to establish effective controls against suspicious orders to prevent prescription drugs from being diverted into the community, including:

- a. Maintaining detailed records of narcotics sold to pharmacies and other retail and health care providers in order to identify and track suspicious orders;
- b. Reporting suspicious orders of controlled substances, including prescription opioids, to alert regulatory and law enforcement officials when it appears that prescription drugs are being diverted for illegal use; and
- c. Identifying suspicious orders, based on knowledge of the legal market for narcotics, and the Distributor Defendants’ unique ability to conduct due diligence.

527. Recognizing a need for greater scrutiny over controlled substances due to their potential for abuse and danger to public health and safety, the United States Congress enacted the Controlled Substances Act in 1970. The CSA and its implementing regulations created a closed-system of distribution for all controlled substances and listed chemicals. Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market. Congress was concerned with the diversion of drugs out of

legitimate channels of distribution and acted to halt the “widespread diversion of [controlled substances] out of legitimate channels into the illegal market.” Moreover, the closed-system was specifically designed to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain. All registrants – which includes all manufacturers and distributors of controlled substances—must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent diversion. When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse. The result is the scourge of addiction that has occurred.

528. The CSA requires manufacturers and distributors of Schedule II substances like opioids to (a) limit sales within a quota set by the DEA for the overall production of Schedule II substances like opioids; (b) register to manufacture or distribute opioids; (c) maintain effective controls against diversion of the controlled substances that they manufacture or distribute; and (d) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales, and report them to the DEA.

529. Central to the closed-system created by the CSA was the directive that the DEA determines quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from “legitimate channels of trade” by controlling the “quantities of the basic ingredients needed for the manufacture of [controlled substances], and the requirement of order forms for all transfers of these drugs.” When evaluating production quotas, the DEA was instructed to consider the following information:

- a. Information provided by the Department of Health and Human Services;
- b. Total net disposal of the basic class of each drug by all manufacturers;
- c. Trends in the national rate of disposal of the basic class of drug;

- d. An applicant's production cycle and current inventory position;
- e. Total actual or estimated inventories of the class of drug and of all substances manufactured from the class and trends in inventory accumulation; and
- f. Other factors such as changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.

530. It is unlawful to manufacture a controlled substance in Schedule II, like prescription opioids, in excess of a quota assigned to that class of controlled substances by the DEA.

531. To ensure that even drugs produced within quota are not diverted, federal regulations issued under the CSA mandate that all registrants, manufacturers and distributors alike, "design and operate a system to disclose to the registrant suspicious orders of controlled substances." 21 C.F.R. § 1301.74(b). Registrants are not entitled to be passive observers, but rather "shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant." *Id.* Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. *Id.* Other red flags may include, for example, "[o]rdering the same controlled substance from multiple distributors."

532. These criteria are disjunctive and are not all-inclusive. For example, if an order deviates substantially from a normal pattern, the order should be reported as suspicious irrespective of the size of the order. Likewise, a distributor or manufacturer need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the responsibility to report the order as suspicious. The determination of whether an order is

suspicious depends not only on the ordering patterns of the particular customer but also on the patterns of the entirety of the customer base and the patterns throughout the relevant segment of the industry. For this reason, identification of suspicious orders serves also to identify excessive volume of the controlled substance being shipped to a particular region.

533. In sum, these Defendants have several responsibilities under state and federal law with respect to control of the supply chain of opioids. First, they must set up a system to prevent diversion, including excessive volume and other suspicious orders. That would include reviewing their own data, relying on their observations of prescribers and pharmacies, and following up on reports or concerns of potential diversion. All suspicious orders must be reported to relevant enforcement authorities. Further, they must also stop the shipment of any order which is flagged as suspicious and only ship orders which were flagged as potentially suspicious if, after conducting due diligence, they can determine that the order is not likely to be diverted into illegal channels.

534. State and federal statutes and regulations reflect a standard of conduct and care below which reasonably prudent manufacturers and distributors would not fall. Together, these laws and industry guidelines make clear that Distributor Defendants and Manufacturer Defendants alike possess and are expected to possess specialized and sophisticated knowledge, skill, information, and understanding of both the market for scheduled prescription narcotics and of the risks and dangers of the diversion of prescription narcotics when the supply chain is not properly controlled.

535. Further, these laws and industry guidelines make clear that the Distributor Defendants and Manufacturer Defendants alike have a duty and responsibility to exercise their specialized and sophisticated knowledge, information, skill, and understanding to prevent the oversupply of prescription opioids and minimize the risk of their diversion into an illicit market.

536. The FTC has recognized the unique role of distributors. Since their inception, Distributor Defendants have continued to integrate vertically by acquiring businesses that are related to the distribution of pharmaceutical products and health care supplies. In addition to the actual distribution of pharmaceuticals, as wholesalers, Distributor Defendants also offer their pharmacy or dispensing, customers a broad range of added services. For example, Distributor Defendants offer their pharmacies sophisticated ordering systems and access to an inventory management system and distribution facility that allows customers to reduce inventory carrying costs. Distributor Defendants are also able to use the combined purchase volume of their customers to negotiate the cost of goods with manufacturers and offer services that include software assistance and other database management support. *See Fed. Trade Comm'n v. Cardinal Health, Inc.*, 12 F. Supp. 2d 34, 41 (D.D.C. 1998) (granting the FTC's motion for preliminary injunction and holding that the potential benefits to customers did not outweigh the potential anti-competitive effect of a proposed merger between Cardinal Health, Inc. and Bergen Brunswig Corp.). As a result of their acquisition of a diverse assortment of related businesses within the pharmaceutical industry, as well as the assortment of additional services they offer, Distributor Defendants have a unique insight into the ordering patterns and activities of their dispensing customers.

537. Manufacturer Defendants also have specialized and detailed knowledge of the potential suspicious prescribing and dispensing of opioids through their regular visits to doctors' offices and pharmacies and from their purchase of data from commercial sources, such as IMS Health. Their extensive boots-on-the-ground through their sales force allows Marking Defendants to observe the signs of suspicious prescribing and dispensing discussed elsewhere in this Complaint—lines of seemingly healthy patients, out-of-state license plates, and cash transactions,

to name only a few. In addition, Manufacturer Defendants regularly mined data, including, upon information, chargeback data, which allowed them to monitor the volume and type of prescribing of doctors, including sudden increases in prescribing and unusual high dose prescribing, which would have alerted them, independent of their sales representatives, to suspicious prescribing. These information points gave Manufacturer Defendants insight into prescribing and dispensing conduct that enabled them to play a valuable role in preventing diversion and fulfilling their obligations under the CSA.

538. Defendants have a duty to be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes.

539. Defendants breached their duties by failing to (a) control the supply chain; (b) prevent diversion; (c) report suspicious orders; and (d) halt shipments of opioids in quantities they knew or should have known could not be justified and were indicative of serious problems of overuse of opioids.

B. Defendants Were Aware of and Have Acknowledged Their Obligations to Prevent Diversion and to Report and Take Steps to Halt Suspicious Orders

540. The reason for the reporting rules is to create a “closed” system intended to control the supply and reduce the diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control. Both because distributors handle such large volumes of controlled substances, and because they are uniquely positioned, based on their knowledge of their customers and orders, as the first line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, distributors’ obligation to maintain effective controls to prevent diversion of controlled substances is critical. Should a distributor

deviate from these checks and balances, the closed system of distribution, designed to prevent diversion, collapses.

541. Defendants were well aware they had an important role to play in this system, and also knew or should have known that their failure to comply with their obligations would have serious consequences.

542. Recently, Mallinckrodt, a prescription opioid manufacturer, admitted in a settlement with DEA that “[a]s a registrant under the CSA, Mallinckrodt had a responsibility to maintain effective controls against diversion, including a requirement that it review and monitor these sales and report suspicious orders to DEA.” Mallinckrodt further stated that it “recognizes the importance of the prevention of diversion of the controlled substances they manufacture” and agreed that it would “design and operate a system that meets the requirements of 21 CFR 1301.74(b) . . . [such that it would] utilize all available transaction information to identify suspicious orders of any Mallinckrodt product.” Mallinckrodt specifically agreed “to notify DEA of any diversion and/or suspicious circumstances involving any Mallinckrodt controlled substances that Mallinckrodt discovers.”

543. Trade organizations to which Defendants belong have acknowledged that wholesale distributors have been responsible for reporting suspicious orders for more than 40 years. The Healthcare Distribution Alliance (“HDA”), formerly known as the Healthcare Distribution Management Association (“HDMA”), a trade association of pharmaceutical distributors to which Distributor Defendants belong, has long taken the position that distributors have responsibilities to “prevent diversion of controlled prescription drugs” not only because they have statutory and regulatory obligations do so, but “as responsible members of society.” Guidelines established by the HDA also explain that distributors, “[a]t the center of a sophisticated

supply chain ... are uniquely situated to perform due diligence in order to help support the security of the controlled substances they deliver to their customers.”

544. The DEA also repeatedly reminded the Defendants of their obligations to report and decline to fill suspicious orders. Responding to the proliferation of pharmacies operating on the internet that arranged illicit sales of enormous volumes of opioids to drug dealers and customers, the DEA began a major push to remind distributors of their obligations to prevent these kinds of abuses and educate them on how to meet these obligations. Since 2007, the DEA has hosted at least five conferences that provided registrants with updated information about diversion trends and regulatory changes. Each of the Distributor Defendants attended at least one of these conferences. The DEA has also briefed wholesalers regarding legal, regulatory, and due diligence responsibilities since 2006. During these briefings, the DEA pointed out the red flags wholesale distributors should look for to identify potential diversion.

545. The DEA also advised in a September 27, 2006 letter to every commercial entity registered to distribute controlled substances that they are “one of the key components of the distribution chain. If the closed system is to function properly ... distributors must be vigilant in deciding whether a prospective customer can be trusted to deliver controlled substances only for lawful purposes. This responsibility is critical, as ... the illegal distribution of controlled substances has a substantial and detrimental effect on the health and general welfare of the American people.” The DEA’s September 27, 2006 letter also expressly reminded them that registrants, in addition to reporting suspicious orders, have a “statutory responsibility to exercise due diligence to avoid filling suspicious orders that might be diverted into other than legitimate medical, scientific, and industrial channels.” The same letter reminds distributors of the importance of their obligation to “be vigilant in deciding whether a prospective customer can be trusted to

deliver controlled substances only for lawful purposes,” and warns that “even just one distributor that uses its DEA registration to facilitate diversion can cause enormous harm.”

546. The DEA sent another letter to Defendants on December 27, 2007, reminding them that, as registered manufacturers and distributors of controlled substances, they share, and must each abide by, statutory and regulatory duties to “maintain effective controls against diversion” and “design and operate a system to disclose to the registrant suspicious orders of controlled substances.” The DEA’s December 27, 2007 letter reiterated the obligation to detect, report, and not fill suspicious orders and provided detailed guidance on what constitutes a suspicious order and how to report (*e.g.*, by specifically identifying an order as suspicious, not merely transmitting data to the DEA). Finally, the letter references the Revocation of Registration issued in *Southwood Pharmaceuticals, Inc.*, 72 Fed. Reg. 36,487-01 (July 3, 2007), which discusses the obligation to report suspicious orders and “some criteria to use when determining whether an order is suspicious.”

C. Defendants Worked Together to Inflate the Quotas of Opioids They Could Distribute

547. Finding it impossible to legally achieve their ever-increasing sales ambitions Defendants engaged in the common purpose of increasing the supply of opioids and fraudulently increasing the quotas that governed the manufacture and distribution of their prescription opioids.

548. Wholesale distributors such as the Distributor Defendants had close financial relationships with both Manufacturer Defendants and customers, for whom they provide a broad range of value-added services that render them uniquely positioned to obtain information and control against diversion. These services often otherwise would not be provided by manufacturers to their dispensing customers and would be difficult and costly for the dispenser to reproduce. For example, wholesalers have sophisticated ordering systems that allow customers to electronically

order and confirm their purchases, as well as to confirm the availability and prices of wholesalers' stock. Through their generic source programs, wholesalers are also able to combine the purchase volumes of customers and negotiate the cost of goods with manufacturers. Wholesalers typically also offer marketing programs, patient services, and other software to assist their dispensing customers.

549. Distributor Defendants had financial incentives from the Manufacturer Defendants to distribute higher volumes, and thus to refrain from reporting or declining to fill suspicious orders. Wholesale drug distributors acquire pharmaceuticals, including opioids, from manufacturers at an established wholesale acquisition cost. Discounts and rebates from this cost may be offered by manufacturers based on market share and volume. As a result, higher volumes may decrease the cost per pill to distributors. Decreased cost per pill in turn, allows wholesale distributors to offer more competitive prices, or alternatively, pocket the difference as additional profit. Either way, increased sales volumes result in increased profits.

550. The Manufacturer Defendants engaged in the practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids as a way to help them boost sales and better target their marketing efforts. The *Washington Post* has described the practice as industry-wide, and the HDA includes a "Contracts and Chargebacks Working Group," suggesting a standard practice. Further, in a recent settlement with the DEA, Mallinckrodt, a prescription opioid manufacturer, acknowledged that "[a]s part of their business model Mallinckrodt collects transaction information, referred to as chargeback data, from their direct customers (distributors)." The transaction information contains data relating to the direct customer sales of controlled substances to 'downstream' registrants," meaning pharmacies or other dispensaries, such as hospitals. Manufacturer Defendants buy data from pharmacies as well. This

exchange of information, upon information, and belief, would have opened channels providing for the exchange of information revealing suspicious orders as well.

551. The contractual relationships among the Defendants also include vault security programs. Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opiates. The manufacturers negotiated agreements whereby the Manufacturer Defendants installed security vaults for the Distributor Defendants in exchange for agreements to maintain minimum sales performance thresholds. These agreements were used by the Defendants as a tool to violate their reporting and diversion duties in order to reach the required sales requirements.

552. In addition, Defendants worked together to achieve their common purpose through trade or other organizations, such as the Pain Care Forum (“PCF”) and the HDA.

553. The Pain Care Forum (“PCF”) has been described as a coalition of drugmakers, trade groups and dozens of non-profit organizations supported by industry funding, including the Front Groups described in this Complaint. The PCF recently became a national news story when it was discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

554. The Center for Public Integrity and The Associated Press obtained “internal documents shed[ding] new light on how drugmakers and their allies shaped the national response to the ongoing wave of prescription opioid abuse.” Specifically, PCF members spent over \$740 million lobbying in the nation’s capital and in all 50 statehouses on an array of issues, including opioid-related measures.

555. The Defendants who stood to profit from expanded prescription opioid use are members of and/or participant in the PCF. In 2012, membership and participating organizations

included Endo, Purdue, Actavis, and Cephalon. Each of the Manufacturer Defendants worked together through the PCF. But, the Manufacturer Defendants were not alone. The Distributor Defendants actively participated, and continue to participate in the PCF, at a minimum, through their trade organization, the HDA. For example, the Executive Committee of the HDA currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc., the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation, and the President, U.S. Pharmaceutical for McKesson Corporation. The Distributor Defendants participated directly in the PCF as well.

556. Additionally, the HDA led to the formation of interpersonal relationships and an organization among the Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Manufacturer Defendants including Actavis, Endo, Purdue, Mallinckrodt, and Cephalon were members of the HDA. Additionally, the HDA and each of the Distributor Defendants, eagerly sought the active membership and participation of the Manufacturer Defendants by advocating for the many benefits of members, including “strengthen[ing] ... alliances.”

557. Beyond strengthening alliances, the benefits of HDA membership included the ability to, among other things, “network one on one with manufacturer executives at HDA’s members-only Business and Leadership Conference,” “networking with HDA wholesale distributor members,” “opportunities to host and sponsor HDA Board of Directors events,” “participate on HDA committees, task forces and working groups with peers and trading partners,” and “make connections.” Clearly, the HDA and the Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships and “alliances” between the Manufacturer and Distributor Defendants.

558. The application for manufacturer membership in the HDA further indicates the level of connection among the Defendants and the level of insight that they had into each other's businesses. For example, the manufacturer membership application must be signed by a "senior company executive," and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company.

559. The HDA application also requests that the manufacturer identify its current distribution information, including the facility name and contact information. Manufacturer members were also asked to identify their "most recent year-end net sales" through wholesale distributors, including the Distributor Defendants, Cardinal Health, and McKesson and their subsidiaries.

560. The closed meetings of the HDA's councils, committees, task forces, and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work closely together, confidentially, to develop and further the common purpose and interests of the enterprise.

561. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Manufacturer Defendants as an opportunity to "bring together high-level executives, thought leaders, and influential managers ... to hold strategic business discussions on the most pressing industry issues." The conferences also gave the Manufacturer and Distributor Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry." The HDA and its conferences were significant opportunities for the Manufacturer and Distributor Defendants to interact at a high level of leadership. It is clear that the Manufacturer Defendants embraced this opportunity by attending and sponsoring these events.

562. After becoming members of HDA, Defendants were eligible to participate on councils, committees, task forces, and working groups, including:

- a. Industry Relations Council: "This council, composed of distributor and manufacturer members, provides leadership on pharmaceutical distribution and supply chain issues."
- b. Business Technology Committee: "This committee provides guidance to HDA and its members through the development of collaborative e-commerce business solutions. The committee's major areas of focus within pharmaceutical distribution include information systems, operational integration and the impact of e-commerce." Participation in this committee includes distributor and manufacturer members.
- c. Logistics Operation Committee: "This committee initiates projects designed to help members enhance the productivity, efficiency and customer satisfaction within the healthcare supply chain. Its major areas of focus include process automation, information systems, operational integration, resource management, and quality improvement." Participation in this committee includes distributor and manufacturer members.
- d. Manufacturer Government Affairs Advisory Committee: "This committee provides a forum for briefing HDA's manufacturer members on federal and state legislative and regulatory activity affecting the pharmaceutical distribution channel. Topics discussed include such issues as prescription drug traceability, distributor licensing, FDA and DEA regulation of distribution, importation, and Medicaid/Medicare reimbursement." Participation in this committee includes manufacturer members.

- e. Contracts and Chargebacks Working Group: “This working group explores how the contract administration process can be streamlined through process improvements or technical efficiencies. It also creates and exchanges industry knowledge of interest to contract and chargeback professionals.” Participation in this group includes manufacturer and distributor members.

563. The Distributor Defendants and Manufacturer Defendants also participated, through the HDA, in Webinars and other meetings designed to exchange detailed information regarding their prescription opioid sales, including purchase orders, acknowledgments, ship notices, and invoices. For example, on April 27, 2011, the HDA offered a Webinar to “accurately and effectively exchange business transactions between distributors and manufacturers...” The Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell prescription opioids.

564. Taken together, the interaction and length of the relationships between and among the Manufacturer and Distributor Defendants reflect a deep level of interaction and cooperation between two groups in a tightly knit industry. The Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids.

565. The HDA and the PCF are merely two examples of the overlapping relationships and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the Defendants were in communication and cooperation.

566. Publications and guidelines issued by the HDA confirm that the Defendants utilized their membership in the HDA to form agreements. Specifically, in the fall of 2008, the HDA published the Industry Compliance Guidelines: Reporting Suspicious Orders and Preventing Diversion of Controlled Substances (the “Industry Compliance Guidelines”) regarding diversion. As the HDA explained in an amicus brief, the Industry Compliance Guidelines were the result of “[a] committee of HDMA members contribut[ing] to the development of this publication” beginning in late 2007.

567. This statement by the HDA and the Industry Compliance Guidelines show that Defendants utilized the HDA to form agreements about their approach to their duties under the CSA. As John M. Gray, President/CEO of the HDA stated to the Energy and Commerce Subcommittee on Health in April 2014, is “difficult to find the right balance between proactive anti-diversion efforts while not inadvertently limiting access to appropriately prescribed and dispensed medications.” Here, it is apparent that all of the Defendants found the same balance—an overwhelming pattern and practice of failing to identify, report, or halt suspicious orders and to prevent diversion.

568. The Defendants’ scheme had a decision-making structure driven by the Manufacturer Defendants and corroborated by the Distributor Defendants. The Manufacturer Defendants worked together to control the state and federal government’s response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion and identify suspicious orders and report them to the DEA.

569. The Defendants worked together to control the flow of information and influence state and federal governments to pass legislation that supported the use of opioids and limited the

authority of law enforcement to rein in illicit or inappropriate prescribing and distribution. The Manufacturer and Distributor Defendants did this through their participation in the PCF and HDA.

570. The Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA remained artificially high and ensured that suspicious orders were not reported to the DEA in order to ensure that the DEA had no basis for refusing to increase or decrease production quotas due to diversion.

571. The Defendants also had reciprocal obligations under the CSA to report suspicious orders of other parties if they became aware of them. Defendants were thus collectively responsible for each other's compliance with their reporting obligations.

572. Defendants thus knew that their own conduct could be reported by other distributors or manufacturers and that their failure to report suspicious orders they filled could be brought to the DEA's attention. As a result, Defendants had an incentive to communicate with each other about the reporting of suspicious orders to ensure consistency in their dealings with DEA.

573. The desired consistency was achieved. As described below, none of the Defendants reported suspicious orders and the flood of opioids continued unimpeded.

D. Defendants Kept Careful Track of Prescribing Data and Knew About Suspicious Orders and Prescribers

574. The data that reveals and/or confirms the identity of each wrongful opioid distributor is hidden from public view in the DEA's confidential ARCOS database. The data necessary to identify with specificity the transactions that were suspicious is in possession of the Defendants but has not been disclosed to the public.

575. Publicly available information confirms that Distributor and Manufacturer Defendants funneled far more opioids into communities across the United States than could have been expected to serve legitimate medical use while intentionally ignoring other red flags of

suspicious orders. This information, along with the information known only to Distributor and Manufacturer Defendants, would have alerted them to potentially suspicious orders of opioids.

576. This publicly available information includes the following facts:

- a. distributors and manufacturers have access to detailed transaction-level data on the sale and distribution of opioids, which can be broken down by zip code, prescriber, and pharmacy and includes the volume of opioids, dose, and the distribution of other controlled and non-controlled substances;
- b. manufacturers make use of that data to target their marketing and, for that purpose, regularly monitor the activity of doctors and pharmacies;
- c. manufacturers and distributors regularly visit pharmacies and doctors to promote and provide their products and services, which allows them to observe red flags of diversion, as described in paragraphs 186 and 200;
- d. Distributor Defendants together account for approximately 90% of all revenues from prescription drug distribution in the United States, and each plays such a large part in the distribution of opioids that its own volume provides a ready vehicle for measuring the overall flow of opioids into a pharmacy or geographic area; and
- e. Manufacturer Defendants purchased chargeback data (in return for discounts to Distributor Defendants) that allowed them to monitor the combined flow of opioids into a pharmacy or geographic area.

577. The conclusion that Defendants were on notice of the problems of abuse and diversion follows inescapably from the fact that they flooded communities with opioids in quantities that they knew or should have known exceeded any legitimate market for opioids-even the wider market for chronic pain.

578. At all relevant times, the Defendants were in possession of national, regional, state, and local prescriber- and patient-level data that allowed them to track prescribing patterns over time. They obtained this information from data companies, including but not limited to: IMS Health, QuintilesIMS, IQVIA, Pharmaceutical Data Services, Source Healthcare Analytics, NDS Health Information Services, Verispan, Quintiles, SDI Health, ArcLight, Scriptline, Wolters Kluwer, and/or PRA Health Science, and all of their predecessors or successors in interest (the “Data Vendors”).

579. The Distributor Defendants developed “know your customer” questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007 was intended to help the Defendants identify suspicious orders or customers who were likely to divert prescription opioids. The “know your customer” questionnaires informed the Defendants of the number of pills that the pharmacies sold, how many non-controlled substances were sold compared to controlled substances, whether the pharmacy buys from other distributors, the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

580. Defendants purchased nationwide, regional, state, and local prescriber- and patient-level data from the Data Vendors that allowed them to track prescribing trends, identify suspicious orders, identify patients who were doctor shopping, identify pill mills, etc. The Data Vendors’ information purchased by the Defendants allowed them to view, analyze, compute, and track their competitors’ sales, and to compare and analyze market share information.

581. IMS Health, for example, provided Defendants with reports detailing prescriber behavior and the number of prescriptions written between competing products.

582. Similarly, Wolters Kluwer, an entity that eventually owned data mining companies that were created by McKesson (Source) and Cardinal Health (ArcLight), provided the Defendants with charts analyzing the weekly prescribing patterns of multiple physicians, organized by territory, regarding competing drugs, and analyzed the market share of those drugs.

583. This information allowed the Defendants to track and identify instances of overprescribing. In fact, one of the Data Vendors' experts testified that the used Data Vendors' information could be used to track, identify, report and halt suspicious orders of controlled substances.

584. Defendants were, therefore, collectively aware of the suspicious orders that flowed daily from their manufacturing and distribution facilities.

585. Defendants refused to identify, investigate and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. As described in detail below, Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012 and 117 recommended decisions in registrant actions from The Office of Administrative Law Judges. These numbers include seventy-six actions involving orders to show cause and forty-one actions involving immediate suspension orders, all for failure to report suspicious orders.

586. Sales representatives were also aware that the prescription opioids they were promoting were being diverted, often with lethal consequences. As a sales representative wrote on a public forum:

Actions have consequences—so some patient gets Rx'd the 80mg OxyContin when they probably could have done okay on the 20mg (but their doctor got "sold" on the 80mg) and their teen son/daughter/child's teen friend finds the pill bottle and takes out a few 80's... next they're at a pill party with other teens and some kid

picks out a green pill from the bowl... they go to sleep and don't wake up (because they don't understand respiratory depression) Stupid decision for a teen to make...yes... but do they really deserve to die?

587. Moreover, Defendants' sales incentives rewarded sales representatives who happened to have pill mills within their territories, enticing those representatives to look the other way even when in-person sales visits to such clinics should have raised numerous red flags. In one example, a pain clinic in South Carolina was diverting massive quantities of OxyContin. People traveled to the clinic from towns as far as 100 miles away to get prescriptions, the DEA's diversion unit raided the clinic, and prosecutors eventually filed criminal charges against the doctors. But Purdue's sales representative for that territory, Eric Wilson, continued to promote OxyContin sales at the clinic. He reportedly told another local physician that this clinic accounted for 40% of the OxyContin sales in his territory. At that time, Wilson was Purdue's top-ranked sales representative. In response to news stories about this clinic, Purdue issued a statement, declaring that "if a doctor is intent on prescribing our medication inappropriately, such activity would continue regardless of whether we contacted the doctor or not."

588. In another example, a Purdue sales manager informed her supervisors in 2009 about a suspected pill mill in Los Angeles, reporting over email that when she visited the clinic with her sales representative, "it was packed with a line out the door, with people who looked like gang members," and that she felt "very certain that this an organized drug ring[.]" She wrote, "This is clearly diversion. Shouldn't the DEA be contacted about this?" But her supervisor at Purdue responded that while they were "considering all angles," it was "really up to [the wholesaler] to make the report." This pill mill was the source of 1.1 million pills trafficked to Everett, Washington, a city of around 100,000 people. Purdue waited until after the clinic was shut down in 2010 to inform the authorities.

589. A Kadian prescriber guide discusses the abuse potential of Kadian. It is full of disclaimers that Actavis has not done any studies on the topic and that the guide is “only intended to assist you in forming your own conclusion.” However, the guide includes the following statements: 1) “unique pharmaceutical formulation of KADIAN may offer some protection from extraction of morphine sulfate for intravenous use by illicit users,” and 2) “KADIAN may be less likely to be abused by health care providers and illicit users” because of “Slow onset of action,” “Lower peak plasma morphine levels than equivalent doses of other formulations of morphine,” “Long duration of action,” and “Minimal fluctuations in peak to trough plasma levels of morphine at steady state.” (p. 1-2). The guide is copyrighted by Actavis in 2007 before Actavis officially purchased Kadian from Alpharma.

590. Defendants’ obligation to report suspicious prescribing ran head-on into their marketing strategy. Defendants did identify doctors who were their most prolific prescribers, but not to report them, but to market to them. It would make little sense to focus on marketing to doctors who may be engaged in improper prescribing only to report them to law enforcement, nor to report those doctors who drove Defendants’ sales.

591. Defendants purchased data from IMS Health (now IQVIA) or other proprietary sources to identify doctors to target for marketing and to monitor their own and competitors’ sales. Marketing visits were focused on increasing, sustaining, or converting the prescriptions of the biggest prescribers, particularly through aggressive, high frequency detailing visits.

592. For example, at a national sales meeting presentation in 2011, Actavis pressed its sales representatives to focus on its high prescribers: “To meet and exceed our quota, we must continue to get Kadian scripts from our loyalists. MCOs will continue to manage the pain products more closely. We MUST have new patient starts or we will fall back into ‘the big leak’. We need

to fill the bucket faster than it leaks.” “The selling message should reflect the opportunity and prescribing preferences of each account. High Kadian Writers / Protect and Grow/ Grow = New Patient Starts and Conversions.” (pg 13). In an example of how new patients + a high volume physician can impact performance: “102% of the quota was achieved by just one high volume physician initiating Kadian on 2-3 new patients per week.”

593. This focus on marketing to the highest prescribers had two impacts. First, it demonstrates that manufacturers were keenly aware of the doctors who were writing large quantities of opioids. But instead of investigating or reporting those doctors, Defendants were singularly focused on maintaining, capturing, or increasing their sales.

594. Whenever examples of opioid diversion and abuse have drawn media attention, Purdue and other Manufacturer Defendants have consistently blamed “bad actors.” For example, in 2001, during a Congressional hearing, Purdue’s attorney Howard Udell answered pointed questions about how it was that Purdue could utilize IMS Health data to assess their marketing efforts but not notice a particularly egregious pill mill in Pennsylvania run by a doctor named Richard Paolino. Udell asserted that Purdue was “fooled” by the doctor: “The picture that is painted in the newspaper [of Dr. Paolino] is of a horrible, bad actor, someone who preyed upon this community, who caused untold suffering. And he fooled us all. He fooled law enforcement. He fooled the DEA. He fooled local law enforcement. He fooled us.”

595. But given the closeness with which Defendants monitored prescribing patterns through IMS Health data, it is highly improbable that they were “fooled.” In fact, a local pharmacist had noticed the volume of prescriptions coming from Paolino’s clinic and alerted authorities. Purdue had the prescribing data from the clinic but alerted no one. Indeed, a Purdue

executive referred to Purdue's tracking system and database as a "gold mine" and acknowledged that Purdue could identify highly suspicious volumes of prescriptions.

596. As discussed below, Endo knew that Opana ER was being widely abused. Yet, the New York Attorney General revealed, based on information obtained in an investigation into Endo, that Endo sales representatives were not aware that they had a duty to report suspicious activity and were not trained on the company's policies or duties to report suspicious activity, and Endo paid bonuses to sales representatives for detailing prescribers who were subsequently arrested for illegal prescribing.

597. Sales representatives making in-person visits to such clinics were likewise not fooled. But as pill mills were lucrative for the manufacturers and individual sales representatives alike, Manufacturer Defendants and their employees turned a collective blind eye, allowing certain clinics to dispense staggering quantities of potent opioids and feigning surprise when the most egregious examples eventually made the nightly news.

E. RDC Failed to Track and Report Suspicious Sales of Opioid Drugs.

598. Defendant RDC is one of the nation's top ten drug wholesalers by volume.

599. RDC is unique from its codefendant distributors in that it is a cooperative business organization whose members include many of its own pharmacy customers, which gives rise to an inherent conflict with its compliance obligations in that its members have a direct financial interest in limiting both pharmacy-level compliance costs and RDC's own compliance costs, and corresponding interests in receiving steady shipments of opioid products.

600. Defendant RDC is a "registrant" under the federal CSA, 21 C.F.R. §1300.02(b), which defines a registrant as any person who is registered with the DEA under 21 U.S.C. § 823. Section 823, in turn, requires pharmacies dispensing Schedule II controlled substances to register with the DEA.

601. Defendant RDC has an obligation to identify "fraudulent prescription drug claims or any information in support thereof," and to not be in "violation of any applicable law, rule and/or regulation."

602. Defendant RDC was aware of its obligations to serve as a safeguard against abuse. Defendant RDC could and should have unilaterally taken action and/or offered a program to third-party payors to accept that: (a) limited to 7 days the supply of opioids dispensed for certain acute prescriptions; (b) reduced the dispensing of stronger and extended-release opioids; (c) enhanced pharmacist counseling for new opioid patients; (d) limited the daily dosage of opioids dispensed based on the strength of the opioid; and (e) required the use of immediate-release formulations of opioids before extended-release opioids are dispensed.

603. Having knowledge and/or notice of prescription opioid abuse, and the damages it was causing to Plaintiffs community, Defendant RDC failed to take other steps to help curb the damages already incurred by Plaintiff due to Defendants, including Defendant RDC, could have: (a) donated medication disposal units to community police departments across the country to ensure unused opioid painkillers are disposed of properly rather than taken by individuals to whom the prescription was not written or otherwise diverted or abused; (b) implemented a program that consists of providing counseling to patients who are receiving an opioid prescription for the first time, such as by discussing the risks of dependence and addiction associated with opioid use and discussing and answering any questions or concerns such patients may have; (c) run public education campaigns in which Defendant RDC ran public education programs; (d) limited to 7 days the supply of opioids dispensed for certain acute prescriptions; (e) reduced the dispensing of stronger and extended release opioids; (f) enhanced pharmacist counseling for new opioid patients; (g) limited the daily dosage of opioids dispensed based on the strength of the opioid; and (h)

required the use of immediate-release formulations of opioids before extended-release opioids are dispensed.

604. Defendant RDC could have and should have implemented these measures at any point in the last 15 years.

605. And the failure to take such steps that Defendant RDC should have taken was negligent and did result in significant damages to Plaintiff and their community.

606. Any and all allegations against the Distributor Defendants and/or the Pharmacy Defendants in this Complaint shall also hereinafter specifically include and be asserted against Defendant RDC, and their DEA registered subsidiaries and affiliates.

607. Defendant RDC had knowledge and/or notice of the damages caused and continuing to be caused by its conduct and could and should have taken measures, including but not limited to those set forth herein, to curb the opioid expansion of opioid use and to prevent or minimize the cascading damages caused by its wrongful conduct.

1. RDC's Fundamentally Flawed Written Policies (or Lack Thereof) Enabled Diversion

608. Prior to 2015, RDC lacked a formal written standard operating procedure governing its compliance with its anti-diversion duties.

609. Prior to 2015, RDC relied on a series of vague and ambiguous policies. In a 2009 letter to the DEA, RDC stated that it established a suspicious order monitoring system that set forth monthly usage thresholds, and that it would prepare "DEA Month End Orders of Suspicion Report" for orders it identified as suspicious.

610. RDC also told the DEA that it would withhold and investigate any "Orders of Interest," which is defined as those exceeding a customer's monthly usage limit.

611. Notwithstanding RDC's 2009 commitments to the DEA, none of these inadequate policies were actually memorialized in a written policy of standard operating procedures made available to the company's employees.

612. In any event, the system described in RDC's 2009 Letter to the DEA was riddled with flaws that enabled diversion. For example, RDC set monthly usage thresholds for its customers by averaging a customer's purchases over a twelve-month period and then multiplying that amount by an arbitrary number that varied based on the class of controlled substance. For schedule II drugs, such as the opioids at issue here, that arbitrary number was three for several years. As such, the thresholds set by RDC's "policy" were invariably so high that customers could not reach them unless their order volumes tripled from their own historical purchasing patterns, rendering the system virtually useless at detecting any suspicious orders. In 2009, RDC had told the DEA that its threshold monitoring system would provide its customers with "room for growth". Indeed, this threshold provided ample room for a scale of growth far exceeding the proportion to meet the needs of any legitimate purposes.

613. In 2012, RDC told the DEA that it would hold all "Orders of Interest" until it received "proper information " from its customers and that if those orders were not released because of "insufficient information" from the pharmacy they would be reported to the DEA as suspicious.

614. Again, RDC's 2012 update to its policies was not actually memorialized in a formal written policy.

615. In 2014, RDC informally implemented a change to its threshold procedures, applying an arbitrary multiplier of two, instead of three, to its customers' historical purchasing

patterns of Schedule II prescription opioids. This still left customers "room to grow" their monthly opioid orders by double their normal volumes before triggering the threshold for scrutiny.

616. At the time, RDC's head of compliance acknowledged major deficiencies in its order monitoring system, writing in an email that the company had lowered its factor multipliers "to force better cooperation from our customers" while referencing "not receiving our loyal pharmacies dispensing records the way we require them."

617. Not until 2015, did RDC finally enact a written Standard Operating Procedure ("SOP") governing its anti-diversion compliance mechanisms. RDC's 2015 SOP, among other things, required the company to (i) obtain and review pharmacy dispensing data prior to selling controlled substances to that pharmacy; (ii) verify customers' DEA registrations; (iii) obtain a completed customer questionnaire requesting information that could disclose red flags of potential diversion; (iv) investigate and hold Orders of Interest; and (v) "assess whether each prospective and current customer dispenses controlled substances for legitimate medical purposes."

618. The 2015 SOP remained fundamentally flawed. For one thing, the SOP did not effectively reform RDC's arbitrary and enabling procedures for setting customers' monthly thresholds; nor did RDC endeavor to conduct any investigation into the appropriateness of its customers' prior average ordering volumes, a failure which effectively rolled all prior diversion activity into the company's future shipments of opioids to those customers. Instead, under the SOP, the arbitrary multiplier for Schedule II drugs was simply cut from two to one and one half. again, meaning that customers had to increase their monthly opioid volumes by 50% before they would even trigger a compliance check by RDC.

619. In addition, the 2015 SOP did not require compliance employees to review dispensing data prior to releasing orders of interest or provide guidance on acceptable justifications for releasing an order of interest or raising a purchase threshold.

620. Further, under the 2015 SOP, RDC continued its longstanding practice of tipping off customers that they were approaching their monthly purchase limits, including when their purchases "reached 75% of their threshold."

621. Moreover, although the 2015 SOP defined suspicious orders as those orders of interest that the company opted not to ship and specified that these orders must be reported to the DEA, it was entirely silent on whether, when, or how suspicious orders should be reported to any State authorities. Nevertheless, even pursuant to the 2015 SOP, RDC failed to adequately design and operate a system to disclose suspicious orders.

622. Finally, as RDC struggled to implement any meaningful compliance program, it also faltered in its mandatory Automation of Reports and Consolidated Orders System ("ARCOS") reporting obligations.

623. In 2013, a DEA audit concluded that RDC had underreported thousands of drug sales made to its customers throughout the Northeast. Following the audit, RDC assured the DEA that it was implementing a new electronic order system that would address any concerns with its order reporting. In June 2014, however, when the DEA reexamined RDC's compliance systems, it discovered that RDC had not implemented the promised new system, and had instead simply failed to enter any of its orders into ARCOS for the entire preceding year.

624. In July 2015, the U.S. Attorney for the Southern District of New York brought a civil complaint against RDC for its failure to report orders in ARCOS, and for failing to report the

loss and/or theft of controlled substances, both in violation of the federal Controlled Substances Act.

625. Shortly thereafter, RDC entered into a settlement agreement with the U.S. Attorney. See Consent Order, United States v. Rochester Drug Cooperative, Case No. 15 Civ. 5219 (S.D.N.Y.) (ECF No. 2; filed July 8, 2015). As part of the agreement, RDC admitted to its failures to report orders and lost/stolen drugs, agreed to pay a \$360,000 fine, and provided the DEA with reconstructed ARCOS data for the preceding five years.

626. On April 23, 2019, RDC and former executives were criminally charged in the Southern District of New York with conspiracy to distribute narcotics, conspiracy to defraud the United States, and failure to file suspicious order reports.

2. RDC's Failure to Effectively Prevent Diversion in Practice

627. Prior to the end of 2013, upon information and belief, RDC's compliance staff consisted of just two individuals. One of these employees handled customer service; the other held the dual responsibilities of managing compliance and operations at RDC's distribution facility - a conflicting and time-competitive function.

628. From approximately 2013 to 2016, RDC spent only about \$150,000 on compliance per year.

629. While the compliance department expanded gradually from 2013 to the present, RDC continued to rely on only a handful of front-line staff to review orders of interest and other due diligence materials for the entirety of its growing customer base- and even after the company expanded to open a second distribution facility.

630. On several occasions, RDC's senior management expressed frustration to compliance employees regarding the costs and the length of time of due diligence reviews. For example, in a 2014 email discussing the hiring of an outside compliance consultant, RDC's then-

CEO, Laurence Doud III, stated that it was ..making me ill as to how much this is going to cost us." In another email, Doud stated "we are wasting a lot of energy and pissing people off," referring to the compliance program and the minimal burden that the program placed on RDC's sales staff.

631. In April of 2019 RDC paid a \$20M fine and agreed to supervision by an independent monitor in exchange for the federal government dropping its charges against the corporation for conspiracy to distribute narcotics, conspiracy to defraud the United States, and failing to file suspicious order report. Former CEO Laurence Doud III was also charged with conspiracy to distribute narcotics and conspiracy to defraud the United States.

632. RDC also failed to provide its compliance with employees with meaningful training and supervision on how to perform various due diligence tasks. Further, it allowed untrained front-line compliance employees to onboard customers, change purchase thresholds, and even ship orders that hit those thresholds without any further review by other staff.

633. As noted above, before 2015, RDC had no written policies governing compliance procedures for onboarding new pharmacy customers. In the absence of such policies, RDC failed to conduct any meaningful due diligence of new customers until at least 2013, when it finally began requiring prospective customers to submit historical dispensing data. Even after adopting the SOP in 2015, on several occasions, RDC approved new customers for the sale of prescription opioids despite the presence of conspicuous red flags. For example, in March 2016, RDC approved the onboarding for the sale of controlled substances to a Queens, New York pharmacy whose dispensing data a compliance employee identified as showing a high percentage of cash purchasers, several out of state prescribers, and prescriptions from a doctor who had been arrested earlier that year on charges stemming from his oxycodone prescribing practices. Similarly, in June 2016, RDC approved the onboarding of another Queens, New York pharmacy despite

acknowledging that the pharmacy's dispensing information showed that it had: (i) high levels of cash payments for controlled substances in violation of the pharmacy's own due diligence policy; (ii) filled controlled substances prescriptions from "prescriber[s] practicing medicine outside the scope of their documented medical specialty"; and (iii) filled prescriptions written for large amounts of known, highly diverted drugs, including "high amounts of oxycodone (prescriptions) for a number of Physicians [sic] Assistants and Nurse practitioners."

634. In 2016, RDC's management directed an override of the SOP instituted only the year before by allowing new customers to purchase prescription opioids and other controlled substances before RDC's compliance team reviewed those customers' dispensing reports, as called for by the SOP. At the time, the company's then-CEO, Mr. Doud, justified the change by stating, "I do not want to slow this down" in referring to the customer onboarding process.

635. RDC not only failed to train its sales employees on how to effectively screen new accounts, it actually incentivized those employees to sign up new customers, without regard for the diversion risk they posed, by offering bonuses of up to \$1,000 for each new account they opened.

636. Despite setting its customers' monthly thresholds at unreasonably high levels, customers still frequently exceeded them. By 2016, for example, RDC had allowed some customers to double their orders for oxycodone and Subsys® within a year.

637. RDC did not conduct due diligence before filling these increasing orders. For example, in February 2015, RDC noted that it had released an order for OxyContin to a Hudson Valley pharmacy without first reviewing the pharmacy's dispensing data. At the time, a compliance employee noted that the order had been shipped "in good faith" based on the promise that the pharmacy would provide updated dispensing data that evening, which it did not. In fact,

the pharmacy had not provided any dispensing data to the company since 2012, and it was further noted that the pharmacy was "loaded" with "Oxyscripts" from an out-of-area doctor that RDC's compliance team was concerned about (the prescriber was, years later, indicted on charges related to his opioid prescribing practices). In May 2015, RDC released an order of the dangerous opioid Subsys® to a Queens pharmacy even though the pharmacy's orders for that drug for the current month were double the pharmacy's average over the previous twelve months. Just prior to that order of interest, a compliance employee had even raised the pharmacy's threshold. RDC shipped the Subsys® order within hours of it being made without updated dispensing data and despite the fact that the order placed the pharmacy over the recently raised threshold for that drug. In July 2015, when a Bronx pharmacy's order of oxycodone hit its purchase threshold, RDC released the order despite acknowledging that in the past the customer had promised to submit dispensing data and had not, and based its approval of the order on a summary report which did not allow the company to view prescriber information or information indicating method of payment- key indicators of potential diversion.

638. On several occasions, RDC even took measures to raise customers' thresholds for opioids without first consulting current dispensing data or documenting justifications for the change. Even when Rochester Drug did block a customer's order that hit a threshold, it routinely took no steps to suspend or terminate those customers pending further investigation, and instead allowed the customer to continue receiving its threshold amount of opioids month after month thereafter.

639. In the four years between 2012 and 2016, RDC consistently underreported suspicious orders to the DEA, reporting at most just four orders during that time period.

640. Even in instances where the company's minimal compliance efforts identified customers whose opioid dispensing demonstrated red flags RDC knew were indicative of diversion, the company failed to report those customers' orders to the DEA or the State as suspicious, let alone terminate, suspend those customers, or refuse to ship opioids to those customers. For example: In 2013, RDC discovered that two Manhattan pharmacy customers were filling a high percentage of cash prescriptions for high dosage oxycodone and other opioids written by a pediatric physician who news reports described as operating an alleged "pill mill." RDC's compliance consultant even noted at the time that the average quantities of opioids dispensed by the pharmacies was, "like a stick of dynamite waiting for DEA to light the fuse."

641. RDC did not file suspicious order reports regarding these pharmacies' orders at the time, and it continued to ship prescription opioids to the pharmacies. In June 2014, RDC's lax due diligence system allowed a Hudson Valley customer to order oxycodone five times over its already inflated threshold for that drug despite the fact that a year before the company had become aware of red flags associated with the customer, including that it was filling prescriptions for out-of-area patients up to 150 miles away. RDC continued to ship to the customer and even shipped orders of interest initially held when the customer hit its threshold without first reviewing or obtaining any dispensing or other information to justify those orders.

642. In November 2015, RDC compliance employees noted that a Manhattan pharmacy had demonstrated a "disturbing" pattern of dispensing oxycodone, including a "staggering" increase in the prior month's order, in which the customer ordered 28,600 units of oxycodone, which nearly doubled the previous six months' ordering average of 15,380 units. The compliance employee also identified high percentages of cash purchases and prescriptions filled by "multiple prescribers using inactive/not found" or otherwise inaccurate DEA registration numbers, out-of-

state prescribers and doctors RDC discovered had been "restricted from practicing medicine in NY State", and multiple doctors on RDC's "Watch list." Despite these red flags of diversion, RDC continued to ship prescription opioids to this customer for more than two years without reporting any of the orders it flagged as suspicious to federal and state authorities.

643. 1805. As another example, RDC continued to ship massive amounts of prescription opioids, including the highly addictive fentanyl drug Subsys® to a mail-order pharmacy in Nassau County, despite numerous red flags and indicia of diversion. Indeed, in 2013, RDC shipped approximately 70,000 grams of opioids to this pharmacy, which represented a more than 400% increase in opioids shipped to the pharmacy when compared to RDC's shipments for the prior year.

644. In addition, in 2013, because of the increased shipments to the pharmacy, RDC engaged an outside consultant to review the pharmacy's due diligence efforts. Following a review, the consultant recommended that RDC ensure that the pharmacy provide it with regular dispensing reports, among other recommendations- and in March of 2013, in response to a report from the consultant, the pharmacy certified in writing that it would provide RDC with "quarterly dispensing reports." But RDC failed to hold the pharmacy to that promise, depriving its front-line compliance employees of critical due diligence information. At one point a compliance employee even commented that it appeared "very suspicious" that the pharmacy had delayed producing updated dispensing information by demanding to review the data prior to its submission.

645. In another instance, despite its history with this pharmacy, RDC did not notice that it lacked dispensing data from the pharmacy for the entire year of 2016 until late-October 2016. RDC identified other red flags at this pharmacy, including multiple high-risk prescribers, but continued to ship it opioids. For instance, in 2014, the pharmacy provided RDC with dispensing data showing that it had filled cash prescriptions for doctors RDC knew were on a "watch list" due

to their prescribing practices. On other occasions, instead of fulfilling its compliance obligations, RDC went out of its way to accommodate the pharmacy's large orders and ignore red flags. In 2014, for example, a RDC brand relationship manager emailed one of the pharmacy's executives to warn the pharmacy to "slow down" on its orders of Fentora®, a fentanyl product, "or give a valid reason that we can share" with the product's manufacturer, noting that RDC had "already sold [it] more than a normal month usage to all customers" for that month and that its ordering was "going to cause red flags." The number of opioids shipped to this pharmacy was within the 99th percentile in the State during the time it was an RDC customer (2012-2017).

646. And in the few cases where RDC decided to stop shipping or otherwise limit its sales of controlled substances to customers following a due diligence investigation, it failed to report the orders of controlled substances that it had already- and very recently- shipped to those customers, despite the suspicions acknowledged internally about those customers' ordering patterns.

647. For example, in 2013, RDC discovered that a number of Bronx pharmacies sharing common ownership were filling cash prescriptions and large amounts of prescriptions for oxycodone, including for a prescriber who did not have an active DEA registration. Indeed, a company sales

648. employee even described how RDC's compliance consultant admitted that, in referring to his site visit to one of the pharmacies, had his visit been a "real DEA audit" the agency would have "gone after their DEA license." Although RDC limited the customer's ability to purchase oxycodone, it did not report the suspicious orders- which it had already shipped to the pharmacy- to the DEA or State authorities. In fact, RDC never submitted a suspicious order report regarding this customer to the DEA or State authorities.

649. RDC had a duty to monitor, identify, detect, report and stop suspicious orders of opioids and prevent the diversion of highly addictive, dangerous opioid drugs, which it failed to do, including, but not limited to, the following:

- Failed to design and operate a compliance system so as to be able to properly detect, prevent and disclose suspicious orders of controlled substances as required by the Controlled Substances Act, applicable DEA regulations and Pennsylvania law;
- Failed to monitor, detect, halt and/or report suspicious orders of unusual size, orders deviating from a normal pattern, and/or orders of unusual frequency to the DEA Field Offices and/or DEA headquarters, as required by and in violation of 21 C.F.R. §1301.74(b), and 21 U.S.C. §842(a)(5);
- Failed to conduct adequate due diligence of its customers, failed to keep and complete and accurate records in the CMSP files maintained for customers and bypassed suspicious order reporting procedures;
- Failed to report suspicious orders for controlled substances in accordance with the standards identified and outlines in the DEA letters; Distributed controlled substances to pharmacies even though those Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed according to prescriptions issued for legitimate medical purposes by practitioners acting in the course of their professional practice, as required by 21 C.F.R. §1306.04(a).
- Failed to decline to ship suspicious orders so as to prevent them from being, and thereby allowed them to be, diverted into illegal channels;
- Failed to help support the security of controlled substances, including the opioid drugs at issue in this case, that they delivered to their customers;
- Distributed and/or dispensed controlled substances, including the opioid drugs at issue in this case, when it was not proper to do so or in the best interests of public health;
- Distributed and sold prescription opioid drugs in Pennsylvania and Bedford County, which they knew were likely to be diverted in Pennsylvania and Bedford County;
- Failed in their duty to investigate and refuse suspicious orders of prescription opioids to the DEA;
- Participated in the diversion of opioid prescription drugs for non-medical purposes and the subsequent opioid crisis ravaging Pennsylvania and the Wilkes-Barre Township, and the damages caused thereby;
- Accepted, upon information and belief, rebates and chargebacks for orders of prescription opioids;
- Identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;
- Failed to maintain proper records of their transactions involving controlled substances and file the proper reports in connection therewith;

- Allowed and facilitated the diversion of opioid prescription drugs into other than legitimate medical, scientific and/or industrial channels;
- Failed to maintain appropriate safeguards and effective controls against the diversion of opioid prescription drugs;
- Failed to report hundreds of suspicious orders from Internet pharmacies that sold drugs online to customers who did not have legal prescriptions;
- Supplied various U.S. pharmacies, including in the Wilkes-Barre Township, with increasing amounts of oxycodone and/or hydrocodone pills, which frequently misused products that helped create the opioid epidemic;
- Failed to investigate orders by interrogating pharmacies and physicians and take the appropriate action to halt suspicious orders before they were filled;
- Unlawfully distributed, sold, dispensed and/or filled, suspicious orders of unusual size, orders deviating substantially from a normal pattern and/or orders of unusual frequency in Pennsylvania and the Wilkes-Barre Township, and/or orders which they knew or should have known were likely to be delivered and/or diverted into Pennsylvania and Bedford County;
- Repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant federal and state authorities.

650. RDC participated in a Drug Diversion Concealment Enterprise as set forth more specifically herein.

651. Defendant RDC's deceptive, unfair, and unconscionable actions and statements about opioids and about its efforts to comply with its duties under Pennsylvania law to prevent abuse and diversion were material, were false, were made with intent to deceive, were made with the intent that the recipient of the information or another party reasonably rely upon it, and were made to further a scheme to defraud consumers and prescribers in violation of Pennsylvania Statutes.

652. Any and all allegations against the Distributor Defendants and/or the Pharmacy Defendants shall also hereinafter specifically include and be asserted against Defendant RDC, and their DEA registered subsidiaries and affiliates.

F. VALUE DRUG Failed to Track and Report Suspicious Sales of Opioid Drugs.

653. Defendant VALUE DRUG COMPANY is a wholesale purchasing and distribution cooperative located in Duncansville, Pennsylvania, that provides pharmaceutical wholesalers, retail and specialty pharmacy services. VALUE DRUG distributes pharmaceuticals, including controlled substances, to approximately 600 independent pharmacies located in Maryland, Pennsylvania, and Ohio.

654. Defendant VALUE DRUG is a "registrant" under the federal CSA, 21 C.F.R. §1300.02(b), which defines a registrant as any person who is registered with the DEA under 21 U.S.C. § 823. Section 823, in turn, requires pharmacies dispensing Schedule II controlled substances register with the DEA.

655. Defendant VALUE DRUG boasts that they offer a wide array of programs and services that enable their member pharmacies to prosper in an increasingly competitive environment while meeting their patients' need for convenient and cost-efficient healthcare, and from specialty pharmacy services to front-end merchandising, their diverse portfolio of offerings helps position-independent pharmacies as healthcare destinations within their communities.

656. In 2011, Defendant VALUE DRUG established Value Specialty Pharmacy, LLC (VSP), a closed-door, URAC and ACHC accredited facility, located in Duncansville, Pennsylvania, to provide independent pharmacies with an option to send specialty prescriptions for fulfillment without utilizing traditional pharmacy benefit managers ("PBM") owned mail order facilities, and to support the needs of independent community pharmacy, in situations when the community pharmacies are unable to fill specialty medications for their patients.

657. Defendant VALUE DRUG claims that VSP is a preferred referral option for patients requiring complex medications for chronic illnesses. They also offer support services to allow some special products to be filled at retail.

658. In addition to Value Specialty Pharmacy, Defendant VALUE DRUG COMPANY offers its co-operative members access to CP Specialty Pharmacy Services™, a hub-based specialty pharmacy services program, which they created in 2016.

659. Defendant VALUE DRUG claims they developed CP Specialty Pharmacy Services to enable community pharmacies to dispense specialty medications at their pharmacy and to help members expand their business and remain competitive.

660. Defendant VALUE DRUG advertises that the CP Specialty Pharmacy Services™ program is available to members at no cost to enroll; and, they claim to provide retail pharmacies with services and resources that prescribers, payers, manufacturers, and patients expect when specialty pharmaceuticals become part of a patient's treatment plan.

661. Defendant VALUE DRUG claims, with CP Specialty Pharmacy Services™, independent pharmacies can provide services locally instead of through an outside resource or pharmacy in another state. The CP Specialty Pharmacy Services™ program contributes to the pharmacist being viewed as a full-service provider, which helps enhance the patient-pharmacist relationship.

662. Defendant VALUE DRUG claims that CP Specialty Pharmacy Services™ is priced competitively and includes: management of the prior authorization process; financial assistance research for patient co-pays over \$100; welcome-to-therapy phone calls detailing drug and disease clinical management; ongoing clinical support and refill reminder phone calls; and 24/7 patient assistance call line.

663. Defendant VALUE DRUG claims they provide sales support training and marketing materials to assist pharmacies in promoting the CP Specialty Pharmacy Services program.

664. Defendant VALUE DRUG has an obligation to identify "fraudulent prescription drug claims or any information in support thereof," and to not be in "violation of any applicable law, rule and/or regulation."

665. Defendant VALUE DRUG was aware of its obligations to serve as a safeguard against abuse. Defendant VALUE DRUG could and should have unilaterally taken action and/or offered a program to third-party payors to accept that: (a) limited to 7 days the supply of opioids dispensed for certain acute prescriptions; (b) reduced the dispensing of stronger and extended-release opioids; (c) enhanced pharmacist counseling for new opioid patients; (d) limited the daily dosage of opioids dispensed based on the strength of the opioid; and (e) required the use of immediate-release formulations of opioids before extended-release opioids are dispensed.

666. Having knowledge and/or notice of prescription opioid abuse, and the damages it was causing to Plaintiff's community, Defendant VALUE DRUG failed to take other steps to help curb the damages already incurred by Plaintiff due to Defendants, including Defendant VALUE DRUG, could have: (a) donated medication disposal units to community police departments across the country to ensure unused opioid painkillers are disposed of properly rather than taken by individuals to whom the prescription was not written or otherwise diverted or abused; (b) implemented a program that consists of providing counseling to patients who are receiving an opioid prescription for the first time, such as by discussing the risks of dependence and addiction associated with opioid use and discussing and answering any questions or concerns such patients may have; (c) run public education campaigns in which Defendant VALUE DRUG ran public

education programs; (d) limited to 7 days the supply of opioids dispensed for certain acute prescriptions; (e) reduced the dispensing of stronger and extended release opioids; (f) enhanced pharmacist counseling for new opioid patients; (g) limited the daily dosage of opioids dispensed based on the strength of the opioid; and (h) required the use of immediate-release formulations of opioids before extended-release opioids are dispensed.

667. Defendant VALUE DRUG could have and should have implemented these measures at any point in the last 15 years.

668. And the failure to take such steps that Defendant VALUE DRUG should have taken was negligent and did result in significant damages to Plaintiff and their community.

669. Defendant VALUE DRUG had the knowledge and/or notice of the damages caused and continues to be caused by its conduct and could and should have taken measures, including but not limited to those set forth herein, to curb opioid expansion of opioid use and to prevent or minimize the cascading damages caused by its wrongful conduct.

670. In June of 2014, Defendant VALUE DRUG agreed to pay \$4,000,000 to the United States to resolve allegations that it violated the Controlled Substances Act (CSA) by failing to report suspicious orders of oxycodone to six pharmacies located in Maryland and Pennsylvania.

671. "Pharmacy wholesalers and retailers that fill unusually large or frequent orders for controlled substances without notifying the DEA violate the law and are subject to penalties," said Attorney for the District of Maryland Rod J. Rosenstein. "Abuse of pharmaceutical drugs is one of the top federal law enforcement priorities."

672. "DEA is responsible for ensuring that all controlled substance transactions take place within DEA regulatory closed system. All legitimate handlers of controlled substances must maintain strict accounting for all distributions and VALUE DRUG failed to adhere to this policy,"

stated Special Agent-in-Charge Karl C. Colder of the Drug Enforcement Administration's Washington Division. "Oxycodone is a very addictive drug and failure to report suspicious orders of oxycodone is a serious matter. The civil penalty levied against VALUE DRUG should send a strong message that all handlers of controlled substances must perform due diligence to ensure the public safety," stated Colder. 789

673. The CSA requires distributors of pharmaceuticals, such as VALUE DRUG, to identify and report suspicious orders of controlled substances, such as orders of unusual size, unusual frequency or those that substantially deviate from a normal pattern. The settlement resolves allegations that from January 1, 2009, through September 12, 2012, VALUE DRUG failed to report suspicious orders of oxycodone to six pharmacy customers, including Russo's Pharmacy in Hagerstown, Maryland; Zonetak Phannacy in Owings Mills, Maryland; Philly Pharmacy- Chestnut Avenue and Philly Pharmacy- Roosevelt Boulevard both located in Philadelphia, Pennsylvania; and East Hills Phannacy and Johnstown Pharmacy, both in Johnstown, Pennsylvania

674. As part of the settlement, VALUE DRUG was required to enter into a Memorandum of Agreement (MOA) with the DEA. The purpose of the MOA was to resolve administrative claims that the DEA had against VALUE DRUG and required that VALUE DRUG implement more effective systems and measures to detect and report suspicious orders of controlled substances. The MOA was to remain in place for a period of three years.

675. Defendant VALUE DRUG had a duty to monitor, identify, detect, report and stop suspicious orders of opioids and prevent the diversion of highly addictive, dangerous opioid drugs, which it failed to do, including, but not limited to, the following:

- Failed to design and operate a compliance system so as to be able to properly detect, prevent and disclose suspicious orders of controlled substances as required by the Controlled Substances Act, applicable DEA regulations and Pennsylvania Law;
- Failed to monitor, detect, halt and/or report suspicious orders of unusual size orders deviating from a normal pattern, and/or orders of unusual frequency to the DEA Field Offices and/or DEA headquarters, as required by and in violation of 21 C.F.R. §1301.74(b), and 21 U.S.C. §842(a)(5);
- Failed to conduct adequate due diligence of its customers, failed to keep and complete and accurate records in the CMSP files maintained for customers and bypassed suspicious order reporting procedures;
- Failed to report suspicious orders for controlled substances in accordance with the standards identified and outlines in the DEA letters;
- Distributed controlled substances to pharmacies even though those Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed according to prescriptions issued for legitimate medical purposes by practitioners acting in the course of their professional practice, as required by 21 C.F.R. §1306.04(a).
- Failed to decline to ship suspicious orders so as to prevent them from being, and thereby allowed them to be, diverted into illegal channels;
- Failed to help support the security of controlled substances, including the opioid drugs at issue in this case, that they delivered to their customers;
- Distributed and/or dispensed controlled substances, including the opioid drugs at issue in this case, when it was not proper to do so or in the best interests of public health;
- Distributed and sold prescription opioid drugs in Pennsylvania and Wilkes- Barre Township, which they knew were likely to be diverted in Pennsylvania and Wilkes-Barre Township;
- Failed in their duty to investigate and refuse suspicious orders of prescription opioids to the DEA;
- Participated in the diversion of opioid prescription drugs for non-medical purposes and the subsequent opioid crisis ravaging Pennsylvania and Wilkes- Barre Township, and the damages caused thereby;
- Accepted, upon information and belief, rebates and chargebacks for orders of prescription opioids;
- Identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;
- Failed to maintain proper records of their transactions involving controlled substances and file the proper reports in connection therewith;
- Allowed and facilitated the diversion of opioid prescription drugs into other than legitimate medical, scientific and/or industrial channels;
- Failed to maintain appropriate safeguards and effective controls against the diversion of opioid prescription drugs;

- Failed to report hundreds of suspicious orders from Internet pharmacies that sold drugs online to customers who did not have legal prescriptions;
- Supplied various U.S. pharmacies, including in Bedford County, with increasing amounts of oxycodone and/or hydrocodone pills, which frequently misused products that helped create the opioid epidemic;
- Failed to investigate orders by interrogating pharmacies and physicians and take the appropriate action to halt suspicious orders before they were filled;
- Unlawfully distributed, sold, dispensed and/or filled, suspicious orders of unusual size, orders deviating substantially from a normal pattern and/or orders of unusual frequency in Pennsylvania and Wilkes-Barre Township, and/or orders which they knew or should have known were likely to be delivered and/or diverted into Pennsylvania and Bedford County;
- Repeated shipments of suspicious orders, over an extended period of time, in violation of public safety statutes, and without reporting the suspicious orders to the relevant federal and state authorities.

676. Defendant VALUE DRUG participated in a Drug Diversion Concealment Enterprise as set forth more specifically herein.

677. Defendant VALUE DRUG's deceptive, unfair, and unconscionable actions and statements about opioids and about its efforts to comply with its duties under Pennsylvania law to prevent abuse and diversion were material, were false, were made with intent to deceive, were made with the intent that the recipient of the information or another party reasonably rely upon it, and were made to further a scheme to defraud consumers and prescribers in violation of Pennsylvania Statutes. 1839. Any and all allegations against the Distributor Defendants and/or the Pharmacy Defendants shall also hereinafter specifically include and be asserted against Defendant VALUE DRUG, and their DEA registered subsidiaries and affiliates.

G. Manufacturer Defendants and Distributor Defendants Failed to Report Suspicious Orders or Otherwise Act to Prevent Diversion

678. As discussed above, Manufacturer Defendants and Distributor Defendants failed to report suspicious orders, prevent diversion, or otherwise control the supply of opioids following into communities across America. Despite the notice described above, and in disregard of their

duties, these Defendants continued to pump massive quantities of opioids despite their obligations to control the supply, prevent diversion, report and take steps to halt suspicious orders.

679. Governmental agencies and regulators have confirmed (and in some cases, Defendants have admitted) that Defendants did not meet their obligations and have uncovered especially blatant wrongdoing.

680. For example, on January 5, 2017, McKesson entered into an Administrative Memorandum Agreement with the DEA wherein it agreed to pay a \$150 million civil penalty for, inter alia, failure to identify and report suspicious orders at its facilities in Aurora, CO; Aurora, IL; Delran, NJ; LaCrosse, WI; Lakeland FL; Landover, MD; La Vista, NE; Livonia, MI; Methuen, MA; Santa Fe Springs, CA; Washington Courthouse, OH; and West Sacramento, CA. McKesson admitted that at various times during the period from January 1, 2009, through the effective date of the Agreement (January 17, 2017) it “did not identify or report to [the] DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters.” Upon information and belief, McKesson engaged in similar wrongful activity in Pennsylvania.

681. McKesson further admitted that, during this time period, it “failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA’s implementing regulations, 21 C.F.R. Part 1300 et seq., at the McKesson Distribution Centers” including the McKesson Distribution Center located in Washington Court House, Ohio. Due to these violations, McKesson agreed to a partial suspension of its authority to distribute controlled substances from certain of its facilities some of which (including the one in

Washington Courthouse, Ohio), investigators found “were supplying pharmacies that sold to criminal drug rings.”

682. Similarly, in 2017, the Department of Justice fined Mallinckrodt \$35 million for failure to report suspicious orders of controlled substances, including opioids, and for violating recordkeeping requirements. The government alleged that “Mallinckrodt failed to design and implement an effective system to detect and report ‘suspicious orders’ for controlled substances—orders that are unusual in their frequency, size, or other patterns . . . [and] Mallinckrodt supplied distributors, and the distributors then supplied various U.S. pharmacies and pain clinics, an increasingly excessive quantity of oxycodone pills without notifying DEA of these suspicious orders.” Upon information and belief, Mallinckrodt engaged in similar wrongful activity in Pennsylvania.

683. On December 23, 2016, Cardinal Health agreed to pay the United States \$44 million to resolve allegations that it violated the Controlled Substances Act in Maryland, Florida and New York by failing to report suspicious orders of controlled substances, including oxycodone, to the DEA. In the settlement agreement, Cardinal Health admitted, accepted, and acknowledged that it had violated the CSA between January 1, 2009, and May 14, 2012, by failing to:

- a. “timely identify suspicious orders of controlled substances and inform the DEA of those orders, as required by 21 C.F.R. §1301.74(b)”;
 - b. “maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels, as required by 21 C.F.R. §1301.74, including the failure to make records and reports required by the CSA or DEA’s regulations for which a penalty may be imposed under 21 U.S.C. §842(a)(5)”;
- and

- c. “execute, fill, cancel, correct, file with the DEA, and otherwise handle DEA ‘Form 222’ order forms and their electronic equivalent for Schedule II controlled substances, as required by 21 U.S.C. §828 and 21 C.F.R. Part 1305.”

684. In 2012, the State of West Virginia sued Cardinal Health, as well as several smaller wholesalers, for numerous causes of action, including violations of the CSA, consumer credit and protection, and antitrust laws and the creation of a public nuisance. Unsealed court records from that case demonstrate that McKesson and Cardinal Health along with McKesson together shipped 423 million pain pills to West Virginia between 2007 and 2012. These quantities alone are sufficient to show that the Defendants failed to control the supply chain or to report and take steps to halt suspicious orders. In 2016, Cardinal Health agreed to settle the West Virginia lawsuit for \$20 million.

685. Upon information and belief, Cardinal Health engaged in similar wrongful activity in Pennsylvania.

686. Thus, it is the various governmental agencies who have alleged or found—and the Defendants themselves who have admitted—that the Defendants, acting in disregard of their duties, pumped massive quantities of opioids into communities around the country despite their obligations to control the supply, prevent diversions, and report and take steps to halt suspicious orders.

H. The National Retail Pharmacies Were on Notice of and Contributed to Illegal Diversion of Prescription Opioids

687. National retail pharmacy chains earned enormous profits by flooding the country with prescription opioids. They were keenly aware of the oversupply of prescription opioids through the extensive data and information they developed and maintained as both distributors and

dispensaries. Yet, instead of taking any meaningful action to stem the flow of opioids into communities, they continued to participate in the oversupply and profit from it.

688. Each of the National Retail Pharmacies does substantial business throughout the United States. This business includes the distribution and dispensing of prescription opioids.

689. The National Retail Pharmacies distributed and dispensed substantial quantities of prescription opioids in Pennsylvania. In addition, they distributed and dispensed substantial quantities of prescription opioids in other states, and these drugs were diverted from these other states to Pennsylvania. The National Retail Pharmacies failed to take meaningful action to stop this diversion despite their knowledge of it and contributed substantially to the diversion problem.

690. The National Retail Pharmacies developed and maintained extensive data on opioids they distributed and dispensed. Through this data, National Retail Pharmacies had direct knowledge of patterns and instances of improper distribution, prescribing, and use of prescription opioids in communities throughout the country, and in Pennsylvania in particular. They used the data to evaluate their own sales activities and workforce. On information and belief, the National Retail Pharmacies also provided Defendants with data regarding, *inter alia*, individual doctors in exchange for rebates or other forms of consideration. The National Retail Pharmacies' data is a valuable resource that they could have employed to stop diversion but they failed to do so.

I. The National Retail Pharmacies Have a Duty to Prevent Diversion

691. Each participant in the supply chain of opioid distribution, including the National Retail Pharmacies, is responsible for preventing diversion of prescription opioids into the illegal market by, among other things, monitoring and reporting suspicious activity.

692. The National Retail Pharmacies, like manufacturers and other distributors, are registrants under the CSA. 21 C.F.R. § 1301.11. Under the CSA, pharmacy registrants are required to "provide effective controls and procedures to guard against theft and diversion of

controlled substances.” See 21 C.F.R. § 1301.71(a). In addition, 21 C.F.R. § 1306.04(a) states, “[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.” Because pharmacies themselves are registrants under the CSA, the duty to prevent diversion lies with the pharmacy entity, not the individual pharmacist alone.

693. The DEA, among others, has provided extensive guidance to pharmacies concerning their duties to the public. The guidance advises pharmacies on how to identify suspicious orders and other evidence of diversion.

694. Suspicious pharmacy orders include orders of unusually large size, orders that are disproportionately large in comparison to the population of a community served by the pharmacy, orders that deviate from a normal pattern and/or orders of unusual frequency and duration, among others.

695. Additional types of suspicious orders include: (1) prescriptions written by a doctor who writes significantly more prescriptions (or in larger quantities or higher doses) for controlled substances compared to other practitioners in the area; (2) prescriptions which should last for a month in legitimate use but are being refilled on a shorter basis; (3) prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time; (4) prescriptions that look “too good” or where the prescriber’s handwriting is too legible; (5) prescriptions with quantities or doses that differ from usual medical usage; (6) prescriptions that do not comply with standard abbreviations and/or contain no abbreviations; (7) photocopied prescriptions; or (8) prescriptions containing different handwriting. Most of the time, these attributes are not difficult to detect and should be easily recognizable by pharmacies.

696. Suspicious pharmacy orders are red flags for, if not direct evidence of, diversion.

697. Other signs of diversion can be observed through data gathered, consolidated, and analyzed by the National Retail Pharmacies themselves. That data allows them to observe patterns or instances of dispensing that are potentially suspicious, of oversupply in particular stores or geographic areas, or of prescribers or facilities that seem to engage in improper prescribing.

698. According to industry standards, if a pharmacy finds evidence of prescription diversion, the local Board of Pharmacy and DEA must be contacted.

699. Despite their legal obligations as registrants under the CSA, the National Retail Pharmacies allowed widespread diversion to occur—and they did so knowingly.

700. Performance metrics and prescription quotas adopted by the National Retail Pharmacies for their retail stores contributed to their failure. Under CVS's Metrics System, for example, pharmacists are directed to meet high goals that make it difficult, if not impossible, to comply with applicable laws and regulations. There is no measurement for pharmacy accuracy or customer safety. Moreover, the bonuses for pharmacists are calculated, in part, on how many prescriptions that pharmacist fills within a year. The result is both deeply troubling and entirely predictable: opioids flowed out of National Retail Pharmacies and into communities throughout the country. The policies remained in place even as the epidemic raged.

701. The performance metric systems rate the pharmacist employees at the stores operated by Retail Chain Pharmacies based solely on productivity. These requirements place significant and unrealistic time pressures on the pharmacists.

702. The Retail Chain Pharmacies measure how many and how quickly prescriptions are filled daily based on store volume. Many of the Retail Chain Pharmacies' locations require pharmacists to fill one prescription every three minutes. The programs may also measure how many telephone calls are made to customers to refill and/or pick up prescriptions; how many flu

shots are given; as well as other pharmacy tasks. All measurements focus on productivity with the end goal of maximizing retail defendants' profits.

703. In addition to the pharmacist's other duties, Retail Chain Pharmacies required their employee pharmacists to fill more than 600 prescriptions per work shift.

704. For example, CVS maintains a "Metrics System" to evaluate performance in its pharmacists. Under CVS's Metrics System, pharmacists are directed to meet high goals that make it difficult, if not impossible, to comply with applicable laws and regulations. There is no measurement for pharmacy accuracy or customer safety. Moreover, the bonuses for pharmacists are calculated, in part, on how many prescriptions that pharmacist fills within a year. Moreover, the bonuses for pharmacists are calculated, in part, on how many prescriptions that pharmacists are able to fill within a year.

705. At the same time that Retail Chain Pharmacies increased demands for productivity, they cut the hours of pharmacy technicians, leaving pharmacists severely understaffed and unable to provide all necessary services.

706. Retail Chain Pharmacies' high-volume and increased-profits business model led to a greater number of errors in dispensing prescriptions, which can result in substantial harm to pharmacy customers.

707. A survey conducted by the Institute for Safe Medication Practices ("ISMP") of 673 pharmacists revealed that 83% believed that distractions due to performance metrics or measured wait times contributed to dispensing errors and that 49% felt specific time measurements were a significant contributing factor.

708. Further, the National Association of Boards of Pharmacy found that performance metrics, which measure the speed and efficiency of prescription workflow—using such parameters

as prescription wait times, percentage of prescriptions filled within a specified time period, number of prescriptions verified, and number of immunizations given per pharmacist shift—may distract pharmacists and impair professional judgment.

709. The practices of applying performance metrics or quotas to pharmacists in the practice of pharmacy may cause distractions that could potentially decrease pharmacists' ability to perform drug utilization review, interact with patients, and maintain attention to detail, which could ultimately lead to unsafe conditions at a pharmacy.

710. The Retail Chain Pharmacies productivity policies are directly at odds with their performance of due diligence obligations required to be performed in conjunction with federal and state law, especially given the higher duty of care associated with the prescription of narcotic opioids.

711. The Retail Chain Pharmacies were negligent in failing to ensure or even permit, pharmacists in their stores to exercise the reasonable care necessary under the circumstances to detect and prevent diversion.

712. Upon information and belief, this problem was compounded by the Pharmacies' failure to adequately train their pharmacists and pharmacy technicians on how to properly and adequately handle prescriptions for opioid painkillers, including what constitutes a proper inquiry into whether a prescription is legitimate, whether a prescription is likely for a condition for which the FDA has approved treatments with opioids, and what measures and/or actions to take when a prescription is identified as phony, false, forged, or otherwise illegal, or when suspicious circumstances are present, including when prescriptions are procured and pills supplied for the purpose of illegal diversion and drug trafficking.

713. Upon information and belief, the National Retail Pharmacies also failed to adequately use data available to them to identify doctors who were writing suspicious numbers of prescriptions and/or prescriptions of suspicious amounts of opioids or to adequately use data available to them to do statistical analysis to prevent the filling of prescriptions that were illegally diverted or otherwise contributed to the opioid crisis.

714. Upon information and belief, the National Retail Pharmacies failed to analyze: (a) the number of opioid prescriptions filled by individual pharmacies relative to the population of the pharmacy's community; (b) the increase in opioid sales relative to past years; (c) the number of opioid prescriptions filled relative to other drugs, and (d) the increase in annual opioid sales relative to the increase in annual sales of other drugs.

715. Upon information and belief, the National Retail Pharmacies also failed to conduct adequate internal or external audits of their opioid sales to identify patterns regarding prescriptions that should not have been filled and to create policies accordingly, or if they conducted such audits, they failed to take any meaningful action as a result.

716. Upon information and belief, the National Retail Pharmacies also failed to effectively respond to concerns raised by their own employees regarding inadequate policies and procedures regarding the filling of opioid prescriptions.

717. The National Retail Pharmacies were, or should have been, fully aware that the number of opioids being distributed and dispensed by them was untenable, and in many areas patently absurd; yet, they did not take meaningful action to investigate or to ensure that they were complying with their duties and obligations under the law with regard to controlled substances.

2. *Multiple Enforcement Actions against the National Retail Pharmacies Confirms their Compliance Failures.*

718. The National Retail Pharmacies have long been on notice of their failure to abide by state and federal laws and regulations governing the distribution and dispensing of prescription opioids. Indeed, several of the National Retail Pharmacies have been repeatedly penalized for their illegal prescription opioid practices. Upon information and belief, based upon the widespread nature of these violations, these enforcement actions are the product of, and confirm, national policies and practices of the National Retail Pharmacies.

a. CVS

719. CVS is one of the largest companies in the world, with annual revenue of more than \$150 billion. According to news reports, it manages medications for nearly 90 million customers at 9,700 retail locations. CVS could be a force for good in connection with the opioid crisis, but like other Defendants, CVS sought profits over people.

720. CVS is a repeat offender and recidivist: the company has paid fines totaling over \$40 million as the result of a series of investigations by the DEA and the United States Department of Justice (“DOJ”). It nonetheless treated these fines as the cost of doing business and has allowed its pharmacies to continue dispensing opioids in quantities significantly higher than any plausible medical need would require, and to continue violating its recordkeeping and dispensing obligations under the CSA.

721. As recently as July 2017, CVS entered into a \$5 million settlement with the U.S. Attorney’s Office for the Eastern District of California regarding allegations that its pharmacies failed to keep and maintain accurate records of Schedule II, III, IV, and V controlled substances.

722. This fine was preceded by numerous others throughout the country.

723. In February 2016, CVS paid \$8 million to settle allegations made by the DEA and the DOJ that from 2008-2012, CVS stores and pharmacists in Maryland violated their duties under the CSA and filling prescriptions with no legitimate medical purpose.

724. In October 2016, CVS paid \$600,000 to settle allegations by the DOJ that stores in Connecticut failed to maintain proper records in accordance with the CSA.

725. In September 2016, CVS entered into a \$795,000 settlement with the Massachusetts Attorney General wherein CVS agreed to require pharmacy staff to access the state's prescription monitoring program website and review a patient's prescription history before dispensing certain opioid drugs.

726. In June 2016, CVS agreed to pay the DOJ \$3.5 million to resolve allegations that 50 of its stores violated the CSA by filling forged prescriptions for controlled substances—mostly addictive painkillers—more than 500 times between 2011 and 2014.

727. In August 2015, CVS entered into a \$450,000 settlement with the U.S. Attorney's Office for the District of Rhode Island to resolve allegations that several of its Rhode Island stores violated the CSA by filling invalid prescriptions and maintaining deficient records. The United States alleged that CVS retail pharmacies in Rhode Island filled a number of forged prescriptions with invalid DEA numbers, and filled multiple prescriptions written by psychiatric nurse practitioners for hydrocodone, despite the fact that these practitioners were not legally permitted to prescribe that drug. Additionally, the government alleged that CVS had recordkeeping deficiencies.

728. In May 2015, CVS agreed to pay a \$22 million penalty following a DEA investigation that found that employees at two pharmacies in Sanford, Florida, had dispensed prescription opioids, "based on prescriptions that had not been issued for legitimate medical

purposes by a health care provider acting in the usual course of professional practice. CVS also acknowledged that its retail pharmacies had a responsibility to dispense only those prescriptions that were issued based on legitimate medical need.”

729. In September 2014, CVS agreed to pay \$1.9 million in civil penalties to resolve allegations it filled prescriptions written by a doctor whose controlled-substance registration had expired.

730. In August 2013, CVS was fined \$350,000 by the Oklahoma Pharmacy Board for improperly selling prescription narcotics in at least five locations in the Oklahoma City metropolitan area.

731. Dating back to 2006, CVS retail pharmacies in Oklahoma and elsewhere intentionally violated the CSA by filling prescriptions signed by prescribers with invalid DEA registration numbers.

b. Rite Aid

732. With approximately 4,600 stores in 31 states and the District of Columbia, Rite Aid is the largest drugstore chain on the East Coast and the third-largest in the United States, with annual revenue of more than \$21 billion.

733. In 2009, as a result of a multi-jurisdictional investigation by the DOJ, Rite Aid and nine of its subsidiaries in eight states were fined \$5 million in civil penalties for its violations of the CSA.

734. The investigation revealed that from 2004 onwards, Rite Aid pharmacies across the country had a pattern of non-compliance with the requirements of the CSA and federal regulations that lead to the diversion of prescription opioids in and around the communities of the Rite Aid

pharmacies investigated. Rite Aid also failed to notify the DEA of losses of controlled substances in violation of 21 USC 842(a)(5) and 21 C.F.R 1301.76(b).

735. Numerous state and federal drug diversion prosecutions have occurred in which prescription opioid pills were procured from National Retail Pharmacies. The allegations in this Complaint do not attempt to identify all these prosecutions, and the information above is merely by way of example.

736. The litany of state and federal actions against the National Retail Pharmacies demonstrate that they routinely, and as a matter of standard operating procedure, violated their legal obligations under the CSA and other laws and regulations that govern the distribution and dispensing of prescription opioids.

737. Throughout the country and in Pennsylvania in particular, the National Retail Pharmacies were or should have been aware of numerous red flags of potentially suspicious activity and diversion.

738. On information and belief, from the catbird seat of their retail pharmacy operations, the National Retail Pharmacies knew or reasonably should have known about the disproportionate flow of opioids into [jurisdiction] and the operation of “pill mills” that generated opioid prescriptions that, by their quantity or nature, were red flags for if not direct evidence of illicit supply and diversion. Additional information was provided by news reports, and state and federal regulatory actions, including prosecutions of pill mills in the area.

739. On information and belief, the National Retail Pharmacies knew or reasonably should have known about the devastating consequences of the oversupply and diversion of prescription opioids, including spiking opioid overdose rates in the community.

740. On information and belief, because of (among others sources of information) regulatory and other actions taken against the National Retail Pharmacies directly, actions taken against others pertaining to prescription opioids obtained from their retail stores, complaints and information from employees and other agents, and the massive volume of opioid prescription drug sale data that they developed and monitored, the National Retail Pharmacies were well aware that their distribution and dispensing activities fell far short of legal requirements.

741. The National Retail Pharmacies' actions and omission in failing to effectively prevent diversion and failing to monitor, report, and prevent suspicious orders have contributed significantly to the opioid crisis by enabling, and failing to prevent, the diversion of opioids.

I. Defendants Delayed a Response to the Opioid Crisis by Pretending to Cooperate with Law Enforcement

742. When a manufacturer or distributor does not report or stop suspicious orders, prescriptions for controlled substances may be written and dispensed to individuals who abuse them or who sell them to others to abuse. This, in turn, fuels and expands the illegal market and results in opioid-related overdoses. Without reporting by those involved in the supply chain, law enforcement may be delayed in taking action—or may not know to take action at all.

743. After being caught failing to comply with particular obligations at particular facilities, Distributor Defendants made broad promises to change their ways and insisted that they sought to be good corporate citizens. As part of McKesson's 2008 Settlement with the DEA, McKesson claimed to have "taken steps to prevent such conduct from occurring in the future," including specific measures delineated in a "Compliance Addendum" to the Settlement. Yet, in 2017, McKesson paid \$150 million to resolve an investigation by the U.S. DOJ for again failing to report suspicious orders of certain drugs, including opioids. Even though McKesson had been sanctioned in 2008 for failure to comply with its legal obligations regarding controlling diversion

and reporting suspicious orders, and even though McKesson had specifically agreed in 2008 that it would no longer violate those obligations, McKesson continued to violate the laws in contrast to its written agreement not to do so.

744. More generally, the Distributor Defendants publicly portrayed themselves as committed to working with law enforcement, opioid manufacturers, and others to prevent diversion of these dangerous drugs. For example, Defendant Cardinal claims that: “We challenge ourselves to best utilize our assets, expertise, and influence to make our communities stronger and our world more sustainable, while governing our activities as a good corporate citizen in compliance with all regulatory requirements and with a belief that doing ‘the right thing’ serves everyone.” Defendant Cardinal likewise claims to “lead [its] industry in anti-diversion strategies to help prevent opioids from being diverted for misuse or abuse.” Along the same lines, it claims to “maintain a sophisticated, state-of-the-art program to identify, block and report to regulators those orders of prescription controlled medications that do not meet [its] strict criteria.” Defendant Cardinal also promotes funding it provides for “Generation Rx,” which funds grants related to prescription drug misuse. A Cardinal executive recently claimed that Cardinal uses “advanced analytics” to monitor its supply chain; Cardinal assured the public it was being “as effective and efficient as possible in constantly monitoring, identifying, and eliminating any outside criminal activity.”

745. Along the same lines, Defendant McKesson publicly claims that its “customized analytics solutions track pharmaceutical product storage, handling and dispensing in real-time at every step of the supply chain process,” creating the impression that McKesson uses this tracking to help prevent diversion. Defendant McKesson has also publicly stated that it has a “best-in-class

controlled substance monitoring program to help identify suspicious orders,” and claimed it is “deeply passionate about curbing the opioid epidemic in our country.”

746. Moreover, in furtherance of their effort to affirmatively conceal their conduct and avoid detection, the Defendants, through their trade associations, HDMA and NACDS, filed an *amicus* brief in *Masters Pharmaceuticals*, which made the following statements:

- a. “HDMA and NACDS members not only have statutory and regulatory responsibilities to guard against diversion of controlled prescription drugs but undertake such efforts as responsible members of society.”
- b. “Distributors take seriously their duty to report suspicious orders, utilizing both computer algorithms and human review to detect suspicious orders based on the generalized information that *is* available to them in the ordering process.”

747. Through the above statements made on their behalf by their trade associations, and other similar statements assuring their continued compliance with their legal obligations, the Defendants not only acknowledged that they understood their obligations under the law, but they further affirmed that their conduct was in compliance with those obligations.

748. Defendant Mallinckrodt similarly claims to be “committed ... to fighting opioid misuse and abuse,” and further asserts that: “In key areas, our initiatives go beyond what is required by law. We address diversion and abuse through a multidimensional approach that includes educational efforts, monitoring for suspicious orders of controlled substances”

749. Other Manufacturer Defendants also misrepresented their compliance with their legal duties and their cooperation with law enforcement. Purdue serves as a hallmark example of such wrongful conduct. Purdue deceptively and unfairly failed to report to authorities illicit or suspicious prescribing of its opioids, even as it has publicly and repeatedly touted its “constructive